

## IN THE MATTER OF

## SCHERING CORPORATION

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF  
SECS. 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

*Docket 9232. Complaint, Sept. 22, 1989--Decision, Oct. 31, 1994*

This consent order prohibits, among other things, a New Jersey manufacturer of the diet product, Fibre Trim, from claiming that any food, food supplement, or drug product provides any appetite suppressant, weight loss, weight control, or weight maintenance benefit without possessing and relying upon competent and reliable scientific evidence to substantiate the claim.

*Appearances*

For the Commission: *Theodore H. Hoppock and Susan Cohn.*

For the respondent: *Joni Lupovitz, Amy E. Hancock, Albert W. Shay, James H. Sneed and Paul J. Pantano, McDermott, Will & Emery, Washington, D.C.*

## COMPLAINT

The Federal Trade Commission, having reason to believe that Schering Corporation ("respondent"), a corporation, has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

PARAGRAPH 1. Respondent Schering Corporation is a New Jersey corporation, with its office and principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey.

PAR. 2. Respondent has advertised, offered for sale, sold and distributed Fibre Trim to the public as a high fiber supplement, and a weight loss and weight control aid.

PAR. 3. For the purposes of Section 12 of the Federal Trade Commission Act, 15 U.S.C. 52, Fibre Trim is a drug or food as defined in Section 15 of the Act, 15 U.S.C. 55.

PAR. 4. The acts or practices of respondent alleged in this complaint have been in or affecting commerce.

PAR. 5. Typical of respondent's advertisements and promotional materials, but not necessarily all-inclusive thereof, are the attached Exhibits A through H. The aforesaid advertisements and promotional materials contain the following statements:

1. "One of the best sources of dietary fiber is Fibre Trim - the safe, all natural aid to weight control developed in Scandinavia." [Exhibit A]
2. "High Fiber Supplement" [Exhibit B]
3. "[Serving size] 5 Fibre Trim Diet Tabs with 8 oz. water, Calories: 5, Dietary fiber (grams): 2.35. [Exhibit G]
4. "Because Fibre Trim extracts its fiber from two food sources, citrus and grain, it too, is an excellent source of both soluble and insoluble fibers." [Exhibit G]
5. "And Fibre Trim even offers you all of fiber's wonderful health benefits as well." [Exhibit E]
6. "Healthy Reasons to take FIBRE TRIM." [Exhibit H]
7. "If your diet has been low in fiber, you may take a few days to adjust to the healthier level of dietary fiber. As a result, a temporary and slight abdominal discomfort may develop, though this soon disappears. This is a positive sign that your digestive system is becoming healthier." [Exhibit F] [emphasis in original]
8. "Take Fibre Trim to ensure a well-balanced, fiber-rich diet, and feel good knowing you're doing something good for yourself." [Exhibit F]
9. "Slims you the natural way - while providing fiber's healthful benefits." [Exhibit B]
10. "Fibre Trim was developed by scientists in Scandinavia and has been tested and enthusiastically received by consumers." [Exhibit A]
11. "It's proven: Fibre Trim has successfully helped European women lose weight and keep it off." [Exhibit D]
12. "A PROVEN, NATURAL WAY TO LOSE WEIGHT" [Exhibit C]
13. "It's sensible: it makes you feel satisfied with less food." [Exhibit D]
14. "Because fiber creates a pleasant feeling of fullness, you'll be satisfied with smaller portions, which means you'll be reducing your calorie intake." [Exhibit A]
15. "Fibre Trim also helps stave off hunger pangs between meals, and keeps those midnight binges at bay." [Exhibit E]
16. "You can even use it for maintenance, to keep those extra pounds from creeping back on again. [Exhibit E]

PAR. 6. Through the use of the statements referred to in paragraph five and others in advertisements and promotional materials not specifically set forth herein, respondent has represented, directly or by implication, that:

1. Fibre Trim is a high fiber supplement.
2. The recommended daily dosage of Fibre Trim provides most of a person's daily requirements of dietary fiber.

3. The recommended dosage of Fibre Trim provides about 2.35 grams of dietary fiber per serving or about seven grams of dietary fiber per day.

PAR. 7. In truth and in fact:

1. Fibre Trim is not a high fiber supplement.
2. The recommended daily dosage of Fibre Trim does not provide most of a person's daily requirements of dietary fiber.
3. The recommended dosage of Fibre Trim does not provide about 2.35 grams of dietary fiber per serving or about seven grams of dietary fiber per day.

Therefore, the representations set forth in paragraph six were, and are, false and misleading.

PAR. 8. Through the use of the statements and representations referred to in paragraphs five and six, and others not specifically set forth herein, respondent has represented, directly or by implication, that at the time it made said representations, respondent possessed and relied upon a reasonable basis for such representations.

PAR. 9. In truth and in fact, at the time respondent made said representations, respondent did not possess and rely upon a reasonable basis for such representations. Therefore, the representation set forth in paragraph eight was, and is, false and misleading.

PAR. 10. Through the use of the statements referred to in paragraph five, and others in advertisements or promotional materials not specifically set forth herein, respondent has represented, directly or by implication, that:

1. Fibre Trim is an effective appetite suppressant, weight loss, weight control or weight maintenance product; and
2. Fibre Trim provides the health benefits associated with a fiber-rich diet or a high intake of dietary fiber from food.

PAR. 11. Through the use of the statements and representations referred to in paragraphs five and ten, and others not specifically set forth herein, respondent has represented, directly or by implication, that at the time it made said representations, respondent possessed and relied upon a reasonable basis for such representations.

PAR. 12. In truth and in fact, at the time respondent made said representations, respondent did not possess and rely upon a reasonable basis for such representations. Therefore, the representation set forth in paragraph eleven was, and is, false and misleading.

PAR. 13. The acts and practices of respondent as alleged in this complaint constitute unfair or deceptive acts or practices in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

Chairman Steiger recused.



# SCHERING CORPORATION

## Complaint

### EXHIBIT A

### Fiber every day— good health

One of the most important things you can do for your health is to eat a diet high in fiber. Fiber is a natural part of many fruits, vegetables, and grains. It helps you feel full, keeps your digestive system moving smoothly, and can help lower your cholesterol and blood sugar levels. Fiber is also important for maintaining a healthy weight.



**Other benefits of fiber**

Fiber helps you feel full, so you can eat less and lose weight. It also helps you feel better about your diet. Fiber is a natural part of many fruits, vegetables, and grains. It helps you feel full, keeps your digestive system moving smoothly, and can help lower your cholesterol and blood sugar levels. Fiber is also important for maintaining a healthy weight.

### Diet and exercise

In order to lose weight, you need to eat a diet that is low in calories and high in fiber. Exercise is also important for burning calories and building muscle. A combination of diet and exercise is the best way to lose weight and maintain it.



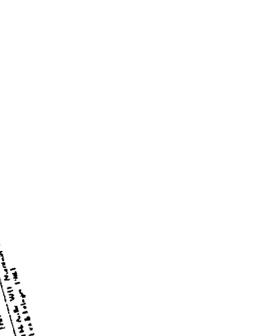
**Calories burned for 30 minutes of activity**

Activity	120 lbs	130 lbs	140 lbs	150 lbs	160 lbs	170 lbs	180 lbs	190 lbs	200 lbs
Walking	120	130	140	150	160	170	180	190	200
Swimming (moderate)	200	210	220	230	240	250	260	270	280
Swimming (vigorous)	250	260	270	280	290	300	310	320	330
Rowing (moderate)	180	190	200	210	220	230	240	250	260
Rowing (vigorous)	220	230	240	250	260	270	280	290	300
Cycling (moderate)	150	160	170	180	190	200	210	220	230
Cycling (vigorous)	200	210	220	230	240	250	260	270	280
Handball	180	190	200	210	220	230	240	250	260
Swimming (water polo)	190	200	210	220	230	240	250	260	270
Swimming (water polo) (vigorous)	200	210	220	230	240	250	260	270	280

\*Calories burned per 30 minutes of activity. Actual calories burned may vary.

### Weight progress chart

Track your weight loss progress with this chart. Record your weight at the beginning and end of each week. The chart shows you how much weight you have lost and how many pounds you still need to lose.



Week	Weight (lbs)	Goal (lbs)
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

### Making fiber a part of your weight loss plan

Fiber is an important part of any weight loss plan. It helps you feel full, so you can eat less. Fiber also helps your digestive system move smoothly, which can help you lose weight. There are many ways to get more fiber in your diet, including eating fruits, vegetables, and grains. Fiber is also available in supplement form. Talk to your doctor about the best way to get more fiber in your diet.

...and other grain products. Avoid foods that are high in fat and sugar, such as fried foods, fast food, and sugary drinks. Instead, choose whole grains, fruits, and vegetables. Fiber is also available in supplement form. Talk to your doctor about the best way to get more fiber in your diet.

...and other grain products. Avoid foods that are high in fat and sugar, such as fried foods, fast food, and sugary drinks. Instead, choose whole grains, fruits, and vegetables. Fiber is also available in supplement form. Talk to your doctor about the best way to get more fiber in your diet.

...and other grain products. Avoid foods that are high in fat and sugar, such as fried foods, fast food, and sugary drinks. Instead, choose whole grains, fruits, and vegetables. Fiber is also available in supplement form. Talk to your doctor about the best way to get more fiber in your diet.



EXHIBIT C



## HOW FIBRE TRIM® GAVE NEW STRENGTH TO THE FRENCH RESISTANCE.

It's never easy to say "no" to food. Especially in a country totally obsessed with it.

Small wonder the French flocked to Fibre Trim: It's a thoroughly natural way to help you fight hunger, and lose weight. A way that works.

When you're not feeling hungry all the time, you can find the strength to say "no" to crêpes, and croissants, and even chocolate-laden éclairs.

In France, they embraced it. In fact, Fibre Trim is so successful, it's Europe's number one diet aid.

Now, it is here.

### A PROVEN, NATURAL WAY TO LOSE WEIGHT

Fibre Trim is natural food fiber. But all fiber is not alike.

Fibre Trim is created from different types of grain and citrus fiber, in a unique blend designed to help you lose weight.



Taken before meals, Fibre Trim helps you eat less without constantly feeling hungry. It can even help you cope with snacking.

### WIN THE DAILY BATTLES, AND THE WAR

Fibre Trim isn't magic. But it's help in a sane, gradual approach to weight loss. Follow the Fibre Trim plan, move around more, and be patient. You may not lose 10 pounds by Thursday, but you'll likely see lasting results.

Since Fibre Trim is simply natural fiber, it can become a sensible way of life—even after you reach your goal. It's the healthy way to stay trim for good.

Take a cue from the food-loving French, and boost your willpower with a little help from Fibre Trim. Vive la resistance!

THE EUROPEAN WAY TO SLIM. FOR GOOD.

*LADIES FIRST SOURCE 7/86*



## EXHIBIT E

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Page 1

# HOW FIBRE TRIM™ CHANGED THE SHAPE OF EUROPE.



It didn't happen overnight.

But gradually  
Europe has taken on  
sleeker new proportions.

Throughout Europe, thousands have been losing weight—and keeping it off—with the help of an intriguing product called Fibre Trim.

It's a thoroughly natural weight loss product. A product so successful for over 5 years, it's the number one diet aid in Europe.

Now, Fibre Trim is here in America.

#### A UNIQUE BLEND OF FIBERS PROVEN IN EUROPE

Fibre Trim contains no drugs of any kind. It's simply a unique combination of natural source fibers specifically balanced to help you eat less, and lose weight.

All fiber is not alike. Fibre Trim contains a blend of four different fibers from grain and

citrus. A blend proven successful all over Europe. A blend that works.

And Fibre Trim even offers you all of fiber's wonderful health benefits as well.

#### TRIUMPH OVER HUNGER PANGS

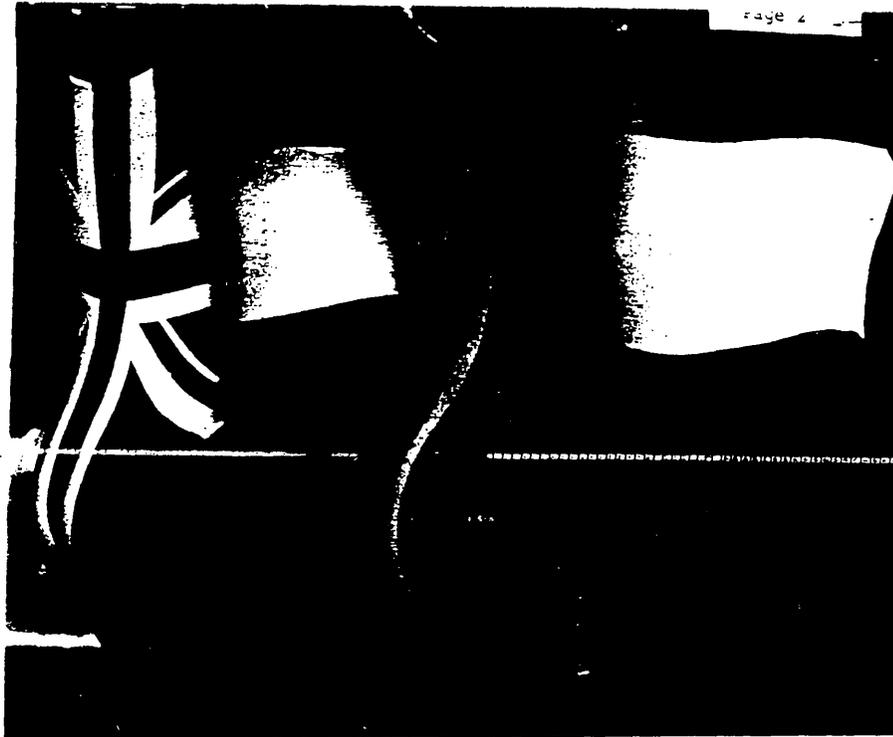
Taken with water before meals, Fibre Trim gives you a pleasant feeling of fullness. So you can still eat normally, but eat less without feeling starved. Fibre Trim also helps stave off hunger pangs between meals, and keeps those midnight binges at bay.

With Fibre Trim, you're fighting hunger without interfering with your body. Because there are no drugs, there are no drug side effects either.

#### GRADUALLY IS THE WAY TO LOSE WEIGHT PERMANENTLY

Fibre Trim is for those who are serious

## EXHIBIT E



about their bodies. People who are smart enough to realize that the results of fad diets almost inevitably evaporate. People with sense enough to know there's just no magical way to lose weight.

You're far more sure of losing weight and keeping it off when you go about it sensibly, and take your time.

That's the Fibre Trim way. A very rational plan designed specifically for gradual weight loss.

SENSIBLE, SO SENSIBLE

Since Fibre Trim offers a safe, natural way to lose weight, it's a program you can live with until you banish

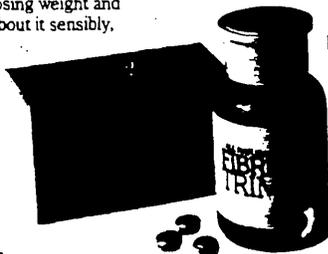
every extra pound. You can even use it for maintenance, to keep those extra pounds from creeping back on again.

But face it. You can't eat cheesecake for breakfast, lunch and dinner and lose weight.

Every dieter knows the basics. Eat right, eat less, and move around more. It's not easy, but Fibre Trim will surely help make it easier.

Because for once, there's a perfectly natural way to lose weight. And keep it off.

Get ready, America. With Fibre Trim, your shape will be changing, too.



THE EUROPEAN WAY TO SLIM. FOR GOOD.

## EXHIBIT F

# FIBRE TRIM.

EXHIBIT F  
Page 1

## YOUR ALL-NATURAL AND SAFE AID TO WEIGHT LOSS

Choosing Fibre Trim to help you lose weight is a sensible decision. After all, it's the #1 diet product in Europe and Canada. Losing excess weight can help you look better, feel better and may contribute to your overall health as well. Fibre Trim is designed to help you lose weight and keep it off—safely, sensibly and without drugs.

### What is Fibre Trim?

- Fibre Trim is an all-natural product, specially developed for weight loss. Through a unique process, concentrated dietary fiber from grain and citrus fruits is compressed into easy-to-take FibreTabs.
- Fibre Trim contains no added sugars or starches, no artificial color or flavor, and no chemical preservatives. It's sodium-free and caffeine-free. And there's only one calorie per FibreTab.
- Fibre Trim contains no drugs of any kind, so you don't have to worry about drug-related side effects commonly associated with many other weight loss products.



### How Fibre Trim Helps You Lose Weight and Keep It Off

- Fibre Trim helps you improve your eating patterns. Its concentrated fiber lets you enjoy the good foods you like, while feeling satisfied with smaller portions. And because Fibre Trim makes you feel satisfied longer, it takes the edge off hunger, helping you reduce between-meal snacking.
- Fibre Trim is your partner—a helper—that makes it easier to stay with your weight loss program because it keeps you satisfied.
- Fibre Trim works naturally, so it works gradually. People who lose weight gradually tend to keep it off. And for assistance in maintaining your ideal weight, Fibre Trim can help. Because it's safe and natural, you can take it as long as you like.

### Fibre Trim—A Healthy Addition to Your Daily Routine

More and more Americans are recognizing the importance of eating right, exercising and keeping fit. We know that when we feel better we look better, and we enjoy life more.

- Results of medical studies indicate that the average person can benefit from increasing the amount of fiber in his or her diet. Fiber-rich diets

have been linked to promoting healthier digestive systems.

- Typical American diets consist largely of processed foods—foods low in fiber. Even though we need more fiber in our diets, it's difficult to consume enough fiber without a lot of extra calories. Fibre Trim is a superior source of dietary fiber. No other food contains as much fiber with so few calories.
- So use Fibre Trim as a daily dietary fiber supplement. Make it as regular a part of your daily routine as brushing your teeth.

Being fit is a new way of life. Avoiding overweight, getting more exercise and including more fiber in your diet are just a few of the steps you can take to better health. Fibre Trim is a natural answer.

### How To Use Fibre Trim

Take five FibreTabs with a large (8 oz.) glass of water three times daily, 15 to 30 minutes before each meal. You'll feel satisfied while eating less.

Once you've reached your weight goal, take two or three FibreTabs before mealtime to help maintain your desired weight and to benefit from the healthier fiber level that Fibre Trim provides.

Should you feel hungry between meals, take two to three additional FibreTabs with a large (8 oz.) glass of water. Since Fibre Trim is a safe, natural food fiber product, you can continue to take it as long as you like.

Note: It is important to use Fibre Trim as recommended with plenty of water over a period of several weeks to achieve the desired long-term effects. Remember, gradual weight loss tends to be long-lasting weight loss.

If your diet has been low in fiber, you may take a few days to adjust to the healthier level of dietary fiber. As a result, a temporary and slight abdominal discomfort may develop, though this soon disappears. This is a positive sign that your digestive system is becoming healthier. Should you experience discomfort, take 3 FibreTabs before each meal for the first few days while your system adjusts to the new fiber level of your diet. Then increase to the usual 5.



## EXHIBIT F

## FIBRE TRIM'S FOUR STEPS TO SLIMNESS

 EXHIBIT F  
Page 2

Follow these four steps to a slimmer figure and healthy weight control.

### 1. Think Thin— Eat Smart!

Think before you eat. The U.S. Dietary Guidelines recommend that Americans eat less sugar, fat, cholesterol, and sodium, and **MORE FIBER** to avoid overweight.

So, eat smaller portions, consume fewer high calorie drinks, and increase your fiber intake.



### 2. Be More Active— Get More Exercise!

This doesn't mean you have to train for a marathon. Any activity—whether walking, running, swimming or cycling—is good for you, makes you feel good and promotes weight control. Be more active and watch the results!



### 3. Be Good to Yourself— Use Fibre Trim Every Day!

Make Fibre Trim a part of your healthier lifestyle. Take Fibre Trim to ensure a well-balanced, fiber-rich diet, and feel good knowing you're doing something good for yourself.



### 4. Keep Your Chin Up and Watch Your Weight Go Down!

Don't give up, don't stop! Keep at it and remember gradual weight loss is healthy weight loss.

### Your Fibre Trim Weight-Loss Progress Chart

Fill in your weight goal and record your progress on this handy chart. And remember, it's important to use Fibre Trim as recommended on a daily basis to achieve the desired long-term effects.

	Date	Pounds
My Weight Now		
My Weight Goal		
My Progress	Date	Weight
2 weeks		
3 weeks		
4 weeks		
5 weeks		
6 weeks		
7 weeks		
8 weeks		

**Don't Forget:** Fibre Trim as suggested three times a day—every day!

**Ingredients:** Natural fiber from grain and citrus fruit, whey protein concentrate (non-nutritive dietary fiber: 44%). Manufactured in Denmark for Schering Corporation.

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**Nutritional Information:** Serving size: 5 tablets. Calories per serving: 5 (1 per FibreTab). Protein: less than 1 gram. Carbohydrate: less than 1 gram. Fat: less than 1 gram. Sodium-free. Contains less than 2% of the U.S. RDA of protein, vitamin A, vitamin C, thiamin, riboflavin, niacin, calcium and iron.

As with any diet plan, consult a health professional before starting your diet.



Complaint

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EXHIBIT G

GETTING STARTED ON THE FIBRE TRIM DIET PLAN

STEP 1: DETERMINE YOUR DESIRABLE WEIGHT

There are several scientific ways to find your ideal weight... weight charts, and more. But you need to go to extremes to find out if you need to shed a few pounds...

STEP 2: SET A REALISTIC WEIGHT LOSS GOAL

To lose weight you need a positive state of mind and a commitment to your goal... Reaching your ideal weight means balancing what you eat against what your body uses for energy...

STEP 3: START A REGULAR ACTIVITY PROGRAM

Adding exercise to your daily routine not only helps you burn calories faster, but makes you look better and feel better about yourself... You don't have to go to extremes when exercising...

STEP 4: START THE FIBRE TRIM DIET

The Fibre Trim Diet provides 1,200 calories and about 30 to 40 grams of dietary fiber daily... The calorie level is the level at which most women are able to lose weight healthfully...

Choose the level that is most comfortable for you... 1,200 calories means you consume a particular diet which is severely restricted in calories...

Table for DAY 1 showing meal breakdown: BREAKFAST (Eggs, Bacon, Toast), LUNCH (Fibre Trim Diet Table, Fruit, Yogurt), DINNER (Fibre Trim Diet Table, Meat, Vegetables, Fruit). Total: 1180 31.2

Table for DAY 2 showing meal breakdown: BREAKFAST (Fibre Trim Diet Table, Fruit, Yogurt), LUNCH (Fibre Trim Diet Table, Fruit, Yogurt), DINNER (Fibre Trim Diet Table, Meat, Vegetables, Fruit). Total: 1200 31.2

Table for DAY 3 showing meal breakdown: BREAKFAST (Fibre Trim Diet Table, Fruit, Yogurt), LUNCH (Fibre Trim Diet Table, Fruit, Yogurt), DINNER (Fibre Trim Diet Table, Meat, Vegetables, Fruit). Total: 1200 31.2

FIBRE TRIM DIET 7-DAY MENU PLAN

The Fibre Trim Diet, based on the nutritional needs of the average healthy adult, provides 1,200 calories. These are 1,500 calories consumed without any additional serving of milk, fruit and raw nuts or bread.

TIPS FOR SUCCESS

- 1. Increase your fluid intake by drinking a glass of water... 2. Weigh down the circumstances under which you eat... 3. Record your weight before you start and keep your progress up to date with a regular weight loss record.

Table for DAY 4 showing meal breakdown: BREAKFAST (Fibre Trim Diet Table, Fruit, Yogurt), LUNCH (Fibre Trim Diet Table, Fruit, Yogurt), DINNER (Fibre Trim Diet Table, Meat, Vegetables, Fruit). Total: 1200 31.2

Table for DAY 5 showing meal breakdown: BREAKFAST (Fibre Trim Diet Table, Fruit, Yogurt), LUNCH (Fibre Trim Diet Table, Fruit, Yogurt), DINNER (Fibre Trim Diet Table, Meat, Vegetables, Fruit). Total: 1200 31.2

Table for DAY 6 showing meal breakdown: BREAKFAST (Fibre Trim Diet Table, Fruit, Yogurt), LUNCH (Fibre Trim Diet Table, Fruit, Yogurt), DINNER (Fibre Trim Diet Table, Meat, Vegetables, Fruit). Total: 1200 31.2

Table for DAY 7 showing meal breakdown: BREAKFAST (Fibre Trim Diet Table, Fruit, Yogurt), LUNCH (Fibre Trim Diet Table, Fruit, Yogurt), DINNER (Fibre Trim Diet Table, Meat, Vegetables, Fruit). Total: 1200 31.2

EXHIBIT H

# Healthy Reasons to Take FIBRE TRIM<sup>®</sup>

Taken with water before meals, Fibre Trim helps you feel pleasantly full. So you can enjoy the foods you like yet be satisfied with eating less. Fibre Trim can also help to curb that between-meal urge to snack.

### How is Fibre Trim Different?

All fiber products are not alike. Developed in Scandinavia, Fibre Trim is a unique blend of four different fibers. A blend that works.

### Fibre Trim Offers a Choice.

Watching your weight may mean cutting back on foods rich in bone-building calcium.

So we also offer Fibre Trim with Calcium. It's just like regular Fibre Trim, but provides 600 mg of calcium in one day's supply.

### Fibre Trim Makes Sense for Everyone.

Medical studies have shown that fiber is important to everyone's health, whether or not you're dieting. And few foods contain as much fiber with so few calories as Fibre Trim.

Watching your weight, getting more exercise and including more fiber in your diet are important to good health. Make Fibre Trim or Fibre Trim with Calcium a part of your healthy lifestyle.



Schering Corporation, Kenilworth, NJ 07033. All rights reserved. 7-080/14-307.

## INITIAL DECISION

BY LEWIS F. PARKER, ADMINISTRATIVE LAW JUDGE  
SEPTEMBER 16, 1991

## I. INTRODUCTION

The Commission issued its complaint in this proceeding on September 22, 1989, charging that respondent Schering Corporation ("Schering") violated Sections 5(a) and 12 of the Federal Trade Commission Act by representing, directly or by implication, that, at the time it made certain claims for its product Fibre Trim, it possessed and relied upon a reasonable basis for such claims, when, in fact, it did not.

The complaint charges in paragraph six, subparagraphs 1, 2, and 3, that Schering, through advertisements and promotional materials, represented, directly or by implication, that:

1. Fibre Trim is a high fiber supplement;
2. The recommended daily dosage of Fibre Trim provides most of a person's daily requirements of dietary fiber;
3. The recommended daily dosage of Fibre Trim provides about 2.35 grams of dietary fiber per serving or about seven grams of dietary fiber per day (Cplt, paragraph 6);<sup>1</sup>

The complaint charges, in paragraph ten, subparagraphs 1 and 2, that Schering represented that:

1. Fibre Trim is an effective appetite suppressant, weight loss, weight control or weight maintenance product; and
2. Fibre Trim provides the health benefits associated with a fiber-rich diet or a high intake of dietary fiber from food (Cplt, paragraph 10).

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<sup>1</sup> The following abbreviations are used in this opinion:

Cplt:	Complaint
Ans.:	Answer
CX:	Commission Exhibit
RX:	Respondent's Exhibit
Tr.:	Transcript
F.:	Finding of Fact
CPF:	Complaint Counsel's Proposed Findings
RPF:	Respondent's Proposed Findings

The complaint charges that since Schering did not possess and rely upon a reasonable basis for the alleged claims, Schering's claims were false and misleading.

Schering's answer admitted the allegations contained in subparagraphs 1 and 3 of paragraph six of the complaint. It also admitted the allegations contained in subparagraph 1 of paragraph ten of the complaint, but denied that it represented Fibre Trim to be an effective appetite suppressant (Ans., paragraphs 6 and 10).

Schering denied the other allegations of paragraphs six and ten.

After extensive discovery, trial was held from January 22, 1991, to March 28, 1991. The parties called several expert witnesses. Those testifying for the Commission were:

Dr. Terence Shimp, a professor of marketing, University of South Carolina (Tr. 52), is an expert in consumer information processing and in judging the likelihood that advertising will leave consumers with particular impressions (Tr. 71).

Dr. Alan Levy, head of the consumer research staff of the Center for Food Safety and Applied Nutrition, Food and Drug Administration (Tr. 188), is a social psychologist and an expert in environmental research methods and health behavior, including consumer awareness of diet and disease relationships (Tr. 189, 199).

Dr. Jon Story, a professor of nutritional physiology, Department of Food and Nutrition, Purdue University, is an expert in nutrition and physiology, particularly in the areas of diets, effects on cholesterol, bile and metabolism, and the effects of dietary fiber (Tr. 472).

Dr. Harry Kissileff, Associate Professor of Clinical Psychology, Department of Psychiatry and Medicine, Columbia University College of Physicians and Surgeons (Tr. 658), is an expert in human eating behavior and its physiological and psychological controls (Tr. 670).

Dr. Alan Levine, Deputy Associate Chief of Staff for Research, Minneapolis Veterans Administration Medical Center (Tr. 748), is an expert in body weight regulation, including the regulation of food intake and energy expenditure (Tr. 759).

Dr. David Levitsky, professor of nutrition and psychology, Cornell University (Tr. 881), is an expert in the control of food intake and body weight, human obesity, statistics and the design of clinical trials (Tr. 911).

Dr. Elaine Lanza, a nutritionist with the National Cancer Institute, National Institute of Health (Tr. 1180), is an expert in nutrition, cancer, the physiological effects of dietary fiber, and the conduct and review of clinical trials involving nutrition intervention, including dietary fiber (Tr. 1209-10).

The following experts testified for Schering:

Elizabeth Fazio, of VOPAN Marketing Research Corporation (Tr. 1794), is an expert in marketing and advertising research (Tr. 1809).

David M. Kweskin, Senior Vice President, Client Services, Ross-Cooper Associates (Tr. 1860-62), is an expert in the design, execution and analysis of consumer research studies, including what messages an advertisement communicates to consumers, the evaluation of products and marketing concepts, and consumers' needs (Tr. 1866-68).

David A. Leury, Vice President and Senior Methodologist, Total Research Corp. (Tr. 1906-07), is an expert in market research (Tr. 1924).

Dr. David Stewart, a professor of marketing, University of Southern California (Tr. 2031), is an expert in advertising, marketing and consumer responses to advertising (Tr. 2039).

Dr. Evelyn Albu, a former Director of Medical Marketing for Schering (Tr. 2176), is an expert in the analysis of medical and scientific literature and the analysis of clinical studies (Tr. 2187).

Dr. Domenic Iezzoni, Director of Medical Services for Schering (Tr. 2393), is an expert in the analysis of the medical validity of reports of clinical trials (Tr. 2405).

Dr. Frank Hurley, a biostatistician and President of Biometric Research Institute (Tr. 2566-67), is an expert in biostatistics, the design, analysis, coordination and management of clinical trials, and Food and Drug Administration requirements for such trials (Tr. 2586).

Dr. Nelson Schimmel, a self-employed consultant and a former Vice President of Regulatory Affairs for Schering (Tr. 2779, 2784), is an expert in the evaluation of scientific and medical literature and clinical trials (Tr. 2787).

Dr. Stig Larsen, a statistician and the President of MEDSTAT, a company which does statistical analyses in epidemiology studies and clinical trials (Tr. 2900-03), is an expert in mathematics, medical statistics, and the statistical evaluation of clinical trials (Tr. 2918).

Dr. David Ahern, a clinical psychologist employed by the Institute for Behavioral Medicine, Providence, R.I. (Tr. 3207), is an expert in the design, conduct and statistical evaluation of clinical trials (Tr. 3220).

Dr. Martin Eastwood, a gastroenterologist, a member of the Faculty of Medicine, University of Edinburgh, and a National Health Service consultant physician (Tr. 3380), is an expert in gastroenterology, human nutrition, the physiological effects of dietary fiber, and the design, conduct and analysis of clinical trials (Tr. 3390).

Dr. Alvan Feinstein, a professor of medicine and epidemiology at the Yale University School of Medicine (Tr. 3534), is an expert in biostatistics, epidemiology and the design, conduct and statistical evaluation of clinical trials (Tr. 3542).

Dr. James Anderson, a physician on the staff of the University of Kentucky Hospital, and a professor of medicine and clinical nutrition with the Hospital (Tr. 3733), is an expert in human nutrition and the physiological effects of dietary fiber (Tr. 3739).

Dr. Joanne Slavin, associate professor of nutrition, Department of Food Science and Nutrition, University of Minnesota (Tr. 3837), is an expert in human nutrition, the physiological effects of dietary fiber on humans, and the design, conduct and analysis of clinical trials (Tr. 3845).

The parties filed their proposed findings of fact and conclusions of law on June 10, 1991. Answers were filed on July 15, 1991. The Commission granted me an extension of time to October 15, 1991, to file this initial decision.

This decision is based on the transcript of testimony, the exhibits which I received in evidence and the proposed findings of fact and conclusions of law and answers thereto filed by the parties. I have adopted several of the proposed findings verbatim. Others have been adopted in substance. All other findings are rejected either because they are not supported by the record or because they are irrelevant.

## II. FINDINGS OF FACT

### A. *The Business Of Schering*

1. Schering, a subsidiary of Schering-Plough, is a corporation organized, existing, and doing business under and by virtue of the

laws of New Jersey, with its offices and principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey (Ans., paragraph 1). Its principal business is the development and marketing of prescription and over-the-counter ("OTC") drugs (Tr. 2411, 2809), such as Afrin, Coricidin, Drixoral and Tinactin (CX 144).

### *B. Schering's Decision To Market Fibre Trim*

2. Farma Food A/S ("Farma Food"), a Danish company headquartered in Copenhagen which was started in the early 1970s principally to develop dietary fiber products, is the manufacturer of Fibre Trim (Tr. 305-06; RX 313, p. 1).

3. Before it was marketed in the United States, Fibre Trim, which is composed of natural fiber from citrus fruit and grain compressed into tablets, was the best selling diet aid in Europe, Canada and other parts of the world (Tr. 305, 1458-59, 1564, 2199; RX 263, RX 313, p. 2, RX 358, p. 1).

4. During negotiations with a pharmaceutical company, A.H. Robbins, regarding another product, Schering was informed that Robbins had considered and rejected marketing Fibre Trim in the United States. After a series of meetings with representatives of Farma Food, Schering decided, in late 1984, to enter into an agreement with Farma Food to market Fibre Trim in the United States (Tr. 305-06, 1456-57, 1471).

5. Charles Bonfield, the Vice President, and later President, of Farma Food's U.S. subsidiary, was the liaison between Farma Food and the Schering marketing department regarding Fibre Trim (Tr. 307-08), and sent Schering a series of letters detailing the characteristics and effects of dietary fiber and the demand for diet products in the United States (Tr. 1464-65). He also gave Schering copies of clinical studies of Fibre Trim's efficacy as a weight loss product (Tr. 308).

6. Since Fibre Trim would be the first non-drug product marketed by Schering, it conducted extensive market research into the proper positioning of Fibre Trim in the diet aids market (Tr. 1468-69, 1499, 1564-65).

7. Consumer research confirmed that because of the increase in obesity in the United States (CX 142, p. 1) a market existed for an all-natural aid to weight loss different from other products, particularly those using Phenylpropanolamine ("PPA") as the active ingredient

since PPA can cause side effects such as nervousness, dizziness and sleeplessness (Tr. 672, 1471-72f 156465, 1602; RX 313, p. 4).

8. The amount of market and consumer research conducted for Fibre Trim was significantly greater than that for other Schering products (Tr. 1499). Schering contracted with several independent market research firms to conduct consumer research prior to test marketing Fibre Trim, while Schering's Marketing Research Department also continued to conduct consumer studies on its own (Tr. 1564-65).

9. Early concept testing showed that greatest consumer interest was generated by positioning Fibre Trim as a sensible way to lose weight. The "sensible" concept became the central message of the Fibre Trim creative strategy and was incorporated into virtually every Fibre Trim advertisement (Tr. 1488, 1579-82, 1589-91, 1824, 1825, 1829, 2053, 2060, 2062-63; RX 240, p. 7).

10. The target audience for Fibre Trim was seen to be females who were relatively sophisticated, intelligent, somewhat upscale economically, and knowledgeable about diet advertising (Tr. 78, 108, 1477; RX 229).

11. After test marketing Fibre Trim from May to August 1985 (Tr. 1494, 1509-70), Schering's top management authorized the marketing department to introduce Fibre Trim nationwide (Tr. 1502, 1514-15, 1642-43). According to Schering, Fibre Trim became the top-selling diet product in its category within a few months of its national introduction (CX 347).

12. During the first year following its introduction in the United States, Schering spent \$16.6 million advertising Fibre Trim and realized \$48.5 million in sales, garnering approximately 17 percent of the diet product market, second only to Thompson Medical's Dexatrim (CX 182, pp. 1, 4). Schering continued to expend significant resources advertising Fibre Trim in 1987, spending \$9.6 million in the first half of the year alone (CX 181, p. 2).

13. Fibre Trim is sold in bottles of 100 or 250 tablets (*e.g.*, CX 351). One-hundred-tablet bottles have accounted for approximately two-thirds of total sales, and 250-tablet bottles have accounted for approximately one-third of sales. The suggested retail price for the 100 and 250-tablet bottles was \$5.99 and \$12.69 (CX 310, p. 3; Tr. 1518).

### C. Jurisdiction

14. Schering has advertised, offered for sale, sold and distributed Fibre Trim to the public as a high fiber supplement, and as a weight loss and weight maintenance product (Ans., paragraph 2).

15. At all times relevant to the complaint, the acts and practices of respondent alleged in the complaint have been in or have affected commerce (Ans., paragraph 4).

### D. Schering's Advertising Of Fibre Trim

#### 1. Introduction

16. The advertisements and promotional materials at issue were disseminated in a long-running advertising campaign, beginning with the test marketing in 1985, and continuing nationwide from January 1986 until the present (Tr. 1594, 1681, 1694, 1726; *see* CX 280). Schering's 1986 advertising expenditures for Fibre Trim of about \$16.6 million were the highest of any diet product (CX 182, pp. 1, 10).

17. Schering's six-year advertising and promotion effort has used television and radio advertisements and promotions, as well as print media, newspaper supplements, free-standing inserts, in-package coupons and direct mail (*see, e.g.*, CX 339, CX 278, CX 291; Tr. 1600-04).

18. Schering also disseminated promotional materials to physicians, pharmacists, retailers and others who sell or recommend the purchase of weight loss products or fiber supplements to consumers (*e.g.*, CX 354, CX 358; Tr. 1734).

19. The test marketing of Fibre Trim, from May - August 1985, used television and print advertisements, free-standing inserts and promotional materials for members of the trade, and reached millions of consumers (Tr. 1502, 1528-29, 1656; CX 321, CX 396).

#### 2. Television Advertisements

20. Among the first advertisements to be disseminated in the national campaign were the 15-second and 30-second versions of the "French Girls" television commercial (CX 339, CX 343, CX 344) which were broadcast on the three major networks or cable networks

during the test marketing in 1985 and at various times through 1989 (CX 368, Interrog. No's. 2, 3, CX 305, CX 316, CX 321, CX 339).

21. The "Take It Off" television commercial (CX 340, CX 343) was broadcast on selected test market television stations in 1985 (CX 368, Interrog. No. 2).

22. The "Italian Men" television commercial (CX 341, CX 343) was broadcast on three networks throughout 1987 (CX 368, Interrog. No. 2).

23. The "English Maids" television commercial (CX 342, CX 343) was broadcast on three networks throughout 1987 (CX 368, Interrog. No. 2, CX 305, p. 2).

24. The 15-second and 30-second versions of the "Enfants" television advertisement (CX 343, CX 344) were broadcast on three networks in 1987 and 1988 (CX 368, Interrog. No. 3, CX 305, CX 316, pp. 1, 2).

### 3. Radio Advertisements

25. The radio advertisement entitled "Interview/Consumer Hotline with Audrey Cross" (CX 291) was distributed to 1,009 radio stations and aired by 313, with a total reach of almost five million listeners (CX 317, p. 1, CX 322, p. 1, CX 368, Interrog. No. 1).

### 4. Print Advertisements

26. Two brochures entitled "Fibre Trim Diet Plan" (CX 284, CX 288) were offered by Audrey Cross on television shows and radio programs during 1986 and 1987. They were also disseminated at retailer displays, physicians' offices, pharmacy counters and by mail request directly from Schering Corporation (CX 368, Interrog. No. 1).

27. The newspaper advertisement entitled "Health Hints, Fiber and Weight Loss" (CX 289) was printed in 4,000 different newspapers during the week of February 19, 1986 (CX 368, Interrog. No. 1).

28. The newspaper advertisement entitled "Quick Quiz" (CX 290) was disseminated to 3,800 different newspapers on April 4, 1986 (CX 318, CX 368, Interrog. No. 1).

29. Five different print advertisements were included as free-standing inserts in Sunday newspaper supplements as follows:

CX 271 -- January 18, 1987  
CX 272 -- February 15, 1987  
CX 278 -- August 10, 1986  
CX 287 -- January 10, 1988  
CX 293 -- April 27, 1986

Schering intended to distribute 47 million copies of CX 293 nationally (RX 254, p. 22).

30. The newspaper advertisement entitled "Fibre Trim Changed The Shape Of Europe" (CX 279) was printed in the Good Health Magazine of The New York Times, in January 1986 (CX 368, Interrog. No. 1).

31. The newspaper advertisement, with a coupon, entitled "Try New Fibre Trim And Save" (CX 387) appeared as a free-standing insert in the test market and in the national launch of the product (Tr. 1627).

32. The advertisement entitled "Shape Up For Summer" (CX 274) appeared in major national magazines such as Health, Weight Watchers and American Health, in May 1987 (CX 368, Interrog. No. 1).

33. The advertisements entitled "Lately, There's A Lot Less To Pinch In Italy" (CX 285) and "How Fibre Trim Stopped The British Pound From Fluctuating" (CX 286) appeared in major national magazines such as Family Circle, Ladies Home Journal, Redbook, Woman's Day, Cosmopolitan, Glamour, Harpers Bazaar, Health, People, Self, and Working Mother, in 1986 (Tr. 1663; CX 310, CX 325, CX 368, Interrog. No. 1).

34. The advertisement entitled "How Fibre Trim Gave New Strength To The French Resistance" (CX 287) was printed in the major national magazine Health, in February 1987 (CX 368, Interrog. No. 1).

35. The advertisement entitled "Fibre Trim Changed The Shape Of Europe" (CX 292) appeared nationally in magazines during the test market (Tr. 1620; CX 368, Interrog. No. 1).

36. The print advertisement entitled "Lose Weight With The Help Of Phenylpropanolamine Hydrochloride" (CX 294) (also called "Pills") appeared in major national magazines such as New Woman, American Health, Ladies Home Journal, Self, Hippocrates, Health, People, US, Working Woman, Redbook, Vogue, Family Circle,

Better Homes and Gardens, Working Mother and Cooking Light, in 1988 (Tr. 1697; CX 368, Interrog. No. 1).

37. Several similar print advertisements entitled "How Fibre Trim Changed The Shape Of Europe" were disseminated. CX 295 was disseminated in magazines in 1986 (CX 368, Interrog. No. 1). CX 296 was disseminated in magazines during the test market in 1985 (CX 368, Interrog. No. 1; *see* Tr. 1520-22, 1525). CX 297 was disseminated in major national magazines, such as Time on June 24, 1985, Newsweek on July 22, 1985, Family Circle on August 13, 1985, Health in August 1985, Ladies Home Journal in August 1985, Redbook in August 1985, Sunset in August 1985, Woman's Day on August 13, 1985, and on September 2, 1985, and in Parade Magazine on August 10, 1985 (CX 368, Interrog. No. 1; *see* Tr. 1520-22). CX 299 [RX 397] was disseminated in early 1986 (CX 368, Interrog. No. 1; Tr. 1620). CX 300 was disseminated in major national magazines, such as Better Homes and Gardens in August 1985, Health in July 1985, Time on June 17, 1985, Newsweek on June 24, 1985, Sunset in July 1985, Good Housekeeping in August 1985 and 1,001 Home Ideas in August 1985 (Tr. 1620; CX 368, Interrog. No. 1).

38. The print advertisement entitled "Healthy Reasons To Take Fibre Trim" (CX 273) was disseminated to the public by direct mail in 1987 (CX 368, Interrog. No. 1).

39. The brochure entitled "Fiber Facts" (CX 275 [RX 356]) was disseminated to consumers through displays set up at retailers, pharmacies and dieticians' and doctors' offices, as well as through other public relations efforts, during the test marketing and the first half of 1986 (CX 368, Interrog. No. 1; Tr. 1628).

40. The advertisement entitled "Fibre Trim Diet Plan" (CX 276) was disseminated to consumers through distribution to retailers for placement on the shelf beside the product in early 1986 (CX 368, Interrog. No. 1).

#### 5. Advertisements to the Trade

41. The print advertisement entitled "There's A New High Fiber Supplement To Help Your Patients Lose Weight. . . ." (CX 349) was distributed to physicians (CX 369, Respondent's Supplemental Responses to Complaint Counsel's Second Set of Interrogatories [hereinafter "S. Interrog."], No. 1).

42. The brochure entitled "For Your Patients Who Have Trouble With Dieting Programs" (CX 354) was distributed through Schering retail representatives, who called on physicians in 1987 (CX 369, S. Interrog. No. 1).

43. The print advertisement entitled "Losing Weight Safely, Sensibly, Gradually. . . ." (CX 346) was published in magazines such as Drug Topics and Drug Store News, which are aimed at pharmacists and pharmaceutical wholesalers (CX 369, S. Interrog. No. 1).

44. The brochures entitled "Get Ready With Fibre Trim" (CX 352) and "Stock Display And Recommend New Fibre Trim" (CX 357) were distributed to pharmacists in 1985 (CX 369, S. Interrog. No. 1).

45. Letters to pharmacists, beginning with "Your Customers Often Ask Your Advice When Choosing A Diet Product" (CX 356) and "Schering Corporation Is Pleased To Introduce A New Unique Diet Product. . . ." (CX 358) were distributed to pharmacists in 1985 (CX 369, S. Interrog. No. 1).

46. The product information sheet entitled "Fibre Trim With Calcium" (CX 347) was distributed to Schering sales personnel in 1987 (CX 369, S. Interrog. No. 1).

47. The brochure entitled "All Natural Fibre Trim, High Fiber Food Supplement" (CX 350) was distributed to Schering sales personnel in the fall of 1986 (CX 369, S. Interrog. No. 1).

48. Two product information sheets entitled "Fibre Trim" (CX 355, 351) were distributed to Schering sales personnel in 1985 and 1986 (CX 369, S. Interrog. No. 1).

49. The product information document entitled "Introducing All Natural Fibre Trim" (CX 353) was distributed to Schering sales personnel in November 1985 (CX 369, S. Interrog. No. 1).

50. Two sales brochures entitled "Fibre Trim" (CX 348) and "New All-Natural Fibre Trim" (CX 359) were distributed to retailers and wholesalers in 1985 (CX 369, S. Interrog. No. 1).

## 6. Inserts

51. The package insert entitled "Fibre Trim" (CX 280) was placed in the Fibre Trim package from 1985 to the present (CX 368, Interrog. No. 1).

*E. The Claims Made In Schering's Advertisements*

## 1. The Health Benefits Claim

*a. The Advertisements*

52. References to health in some of the Fibre Trim advertisements were intended to convey the message that it is a healthy, natural way to lose weight and to differentiate it from drug-based diet products (Tr. 1625-26): "And since Fibre Trim is nothing but natural fiber, it can become a healthy way of life. A way to stay slim long after the party's over" (RX 396). "Increasing the amount of fiber in your diet is a healthy way to help you take the pounds off and keep them off naturally" (RX 353; CX 275). "Since Fibre Trim is simply natural fiber, it can become a sensible way of life -- even after you reach your goal. It's the healthy way to stay trim for good" (RX 355; CX 287). "Being fit is a new way of life. Avoiding overweight, getting more exercise and including more fiber in your diet are just a few of the steps you can take to better health" (RX 358; CX 280).

53. However, other Fibre Trim advertisements go beyond the claim that Fibre Trim is a healthy way to lose weight and emphasize the health benefits associated with dietary fiber without regard to Fibre Trim's primary use as a weight loss aid. For example, the headline of CX 273 "Healthy Reasons to Take Fibre Trim" suggests that there are reasons, not a single reason, to use Fibre Trim, and other language states that these reasons involve health, not simply diet: "Medical studies have shown that fiber is important to everyone's health, whether or not you're dieting" (emphasis added).

54. Other advertisements stress the health benefits of fiber without limiting them to those associated with a reduced calorie diet:

CX 275 states that "fiber is essential for good nutrition and good health," that Fibre Trim may be used to "maintain your overall good health," and that it is one of the best sources of dietary fiber.

The Fibre Trim package insert, CX 280, states: "Fibre Trim -- A Healthy Addition to Your Daily Routine," claims that medical studies have shown that "[f]iber-rich diets have been linked to promoting healthier digestive systems," and concludes that "Fibre Trim is a superior source of dietary fiber. No other food contains as much fiber with so few calories" (emphasis in original).

Various versions of the “Shape of Europe” advertisement state that Fibre Trim provides “all of fiber’s wonderful health benefits to boot” (CX 295, CX 296, CX 297, CX 300) or “fiber’s health benefits” (CX 278, CX 293).

Other advertisements state that “Fibre Trim provides needed fiber that many doctors, nutritionists, and scientists have been saying we lack in our diets” (CX 279, p. 2, CX 292, p. 1).

Fibre Trim advertisements disseminated to retailers, pharmacists, or other members of the trade refer to fiber’s health benefits.

Healthy--adds beneficial dietary fiber... superior source of low-calorie fiber... Fiber-rich diets linked to healthier digestive systems (CX 266).

Fibre Trim contributes to the daily intake of dietary fiber, an essential component of good health (CX 349).

[Fibre Trim provides] the healthy benefits of fiber supplementation (CX 352).

You’ve been hearing about the benefits of fiber for years. Now you have convenient Fibre Trim. . . . (CX 356, CX 358).

55. After reviewing Schering’s advertisements, Dr. Shimp concluded that they made product claims related to health by associating one object, Fibre Trim, with another object, fiber, and by explicitly and implicitly asserting that Fibre Trim will provide the same health benefits that fiber or fiber-rich foods provide (CX 266, CX 273, CX 275, CX 278, CX 279, CX 280, CX 292, CX 293, CX 296, CX 295, CX 297; Tr. 123-25, 128-30, 133-34, 136-37, 138-42, 146-50).

56. After reviewing Dr. Shimp’s analysis and the advertisements in question, I find that they make the claim that Fibre Trim provides the health benefits associated with a fiber-rich diet or a high intake of dietary fiber from food. Although the advertisements do not specify the particular benefits that Fibre Trim will provide, they do represent that whatever health benefits the individual consumer associates with fiber will be provided by taking Fibre Trim (*see, e.g.*, Tr. 124-25 re CX 273; Tr. 137 re CX 296). The FDA’s health and diet surveys reveal the health benefits that consumers associate with fiber.

*b. The FDA’s Health and Diet Surveys*

57. The Health and Diet Survey is a biennial telephone survey conducted by the Food and Drug Administration (“FDA”) which

focuses on consumers' knowledge of diet and health issues (Tr. 190-91, 205). The survey's sample size is composed of approximately 4,000 respondents who are randomly subdivided into four equal sub-samples called "replicates." The questions are different for each replicate, each addressing the same topics from different perspectives. In essence, the Health and Diet Survey is four related, but different, surveys (Tr. 196, 205-07).

58. The 1986 Survey included a number of questions relating to consumer understanding of the health effects of fiber, and Dr. Levy of the FDA testified to conclusions which can be drawn from responses to those questions (CX 103; Tr. 211).

59. Question 41 in the fourth replicate asked respondents if they had "heard about any health problems that might be related to how much or how little fiber people consume?" (Tr. 211; CX 2103, p. 13). Only if they responded "yes" to this screener question were they asked question 42, an open-ended question: "What health problems might be related to not consuming enough fiber?" (CX 103, p. 14; Tr. 212). Question 42 was followed by a probe: "Are there any other problems that might be related to not consuming enough fiber?" (CX 103, p. 14; Tr. 212).

60. In response to question 41, 57% of the replicate said they had heard of health effects associated with fiber; they were then asked question 42 (Tr. 213; CX 103, p. 42). Thirty-nine percent of the replicate sample of 1,000 respondents mentioned cancer as a health problem related to not consuming enough fiber (Tr. 214; CX 382, p. 1). Of those respondents who were more articulate and specified a particular form of cancer, 28% mentioned cancer of the colon, intestines or bowels as a health problem related to insufficient fiber (Tr. 215; CX 282, p. 2).

61. Forty-nine percent of those respondents with more than a high school education believed cancer to be related to insufficient fiber consumption. Women were significantly more likely than men to mention cancer as a health problem related to not consuming enough fiber (Tr. 218-19).

62. Its laxative effect was the next most frequently mentioned effect of fiber (14%) (Tr. 216; CX 382, p. 2).

63. Respondents in the third replicate were asked question 33: "Have you heard about any things people could eat or drink that might help prevent cancer?" (CX 103, p. 11; Tr. 210, 220). Those who responded affirmatively were then asked question 34: "What

things could people eat or drink that might help prevent cancer?" This open-ended question was followed with the probe "are there any other things that people eat or drink that might help prevent cancer?," providing an opportunity for respondents to supply up to four answers (CX 103, p. 11). Thirty-two percent of the 1,000 subjects in this replicate responded that fiber was a cancer preventative (Tr. 221-22; CX 103, p. 54).

64. Respondents in the second replicate were asked "What about cancer of the colon, rectum, or intestines: As you understand it, what things might make people more likely to get these cancers?" (CX 103, p. 8 (question 25); Tr. 224-25). In response to this open-ended question, which, unlike the two previously discussed questions, was not limited to dietary factors, approximately 29% mentioned "too little fiber" as a risk factor for developing these cancers (Tr. 226; CX 103, p. 38).

65. Dr. Levy concluded that in 1986, the most frequently mentioned cancer preventative was fiber consumption and that upscale consumers, Fibre Trim's target market, were even more likely to make this association (Tr. 223-26).

66. The 1988 Survey produced similar results: 25% of the respondents in replicate C mentioned cancer, the most frequently given response, as a health problem associated with not consuming enough fiber (Tr. 232; CX 105, p. 29). The laxative effect of fiber was also a frequently mentioned health benefit (Tr. 233). Twenty-eight percent of respondents in replicate B answered that fiber was a cancer preventative (Tr. 235-36; CX 105, p. 6), and Dr. Levy stated that the 1988 Survey revealed that the public considered fiber to be the primary dietary factor related to cancer prevention (Tr. 238).

67. Twenty-one percent of the respondents in the B replicate named fiber as something one could eat that might prevent heart attacks or lower blood cholesterol (Tr. 239-40; CX 105, pp. 5, 129, 139). Forty-three percent of respondents in the A replicate stated that eating more high-fiber foods might have a large effect in preventing heart disease or heart attack, and 38% responded that it might have a moderate effect (Tr. 243-44; CX 105, p. 38).

68. The results of the 1986 and 1988 surveys represent the knowledge and attitude of the U.S. population as a whole with respect to the relationship between fiber and disease and can be used to determine their interpretation of advertising claims for fiber (Tr. 248-50).

69. The responses to the 1986 and 1988 surveys demonstrate that cancer prevention was the primary benefit that consumers associated with a high fiber diet and that a considerable portion of the population also associates such a diet with reduction in the risk of heart disease. The laxative effect of fiber was also mentioned by a significant number of survey respondents.

*c. The Views of Schering Employees*

70. Mr. Walsh, the senior director of OTC marketing for Schering, was responsible for approving draft advertising copy for Fibre Trim; he testified that the language in CX 296 “Fibre Trim even offers all of fiber’s wonderful health benefits to boot” suggests that “whatever those healthy things that you can gain from fiber as it relates to the diet you would get from this product” (Tr. 1525-26).

71. Dr. Albu, the head of Schering’s professional services department, testified that the claim in CX 297 that “Fibre Trim even offers you all of fiber’s wonderful health benefits to boot” was supported because “fiber is fiber,” and therefore whatever health benefits are provided by fiber-containing foods are also provided by Fibre Trim, and that the health benefits associated in the literature with increased fiber intake included reduced risk of colon cancer and reduction in serum cholesterol (Tr. 2365-66). Dr. Iezzoni, who was responsible for the medical department’s review of Fibre Trim advertisements, gave similar testimony (Tr. 2536, 2547-49).

72. Sharon McGee, a senior brand manager who was responsible for the Fibre Trim brand from October 1984 through February 1987, testified that Schering undertook a public relations campaign to “[c]reate a positive environment among consumers for the benefits of fiber for . . . general health prior to the start of advertising” (Tr. 1558, 1604-05; CX 308, p. 10).

73. Materials which Schering provided to its sales force contain many references to the health benefits of fiber, including cancer prevention, cholesterol reduction and treatment of diabetes and diverticulosis (CX 142, pp. 42-46, CX 143, pp. 10, 11, 13, 16, 19, 20, 27-28), and Schering knew that consumer “awareness of the benefits of a diet rich in fiber is rising” (CX 143, p. 17):

There is not a week without an article on fiber in a health or women’s magazine. The introduction of FIBRE TRIM is, as you can see, very timely. FIBRE TRIM will benefit from this favorable environment. *Id.*

74. In materials it disseminated at the press conference announcing the national launch of Fibre Trim (CX 310, p. 13; *see* Tr. 1517), Schering claimed that dietary fiber had value in preventing some digestive conditions and that high fiber diets may reduce the risk for certain kinds of colon cancer. Those same materials stated that “[o]ne of the best sources of dietary fiber is FIBRE TRIM. . . .” (CX 310, p. 16).

*d. Schering’s Consumer Research*

75. Dr. Stewart, Schering’s advertising expert, testified that no advertisements for Fibre Trim made express claims that it provides the health benefits associated with a fiber-rich diet or a high intake of dietary fiber from food (Tr. 2091) and Dr. Shimp agreed that Fibre Trim advertisements which he was questioned about do not specify any particular health benefits provided by Fibre Trim (Tr. 124, 137).

76. Dr. Stewart also testified that the following research conducted by or for Schering reveals that consumers did not take away from Fibre Trim advertisements the message that it will provide the health benefits associated with a diet rich in fiber or a high intake of dietary fiber (Tr. 2057-76).

- (1) Initial Focus Group Consumer Testing: “In Search of A Concept Statement For Fiber [sic] Trim,”  
(Marketing Perceptions, Inc.) (November 1984)

77. In October 1984, at Schering’s request, the market research firm, Marketing Perceptions, Inc. (“Marketing Perceptions”), conducted initial diet market consumer focus groups relating to Fibre Trim (Tr. 1469, 1564; RX 235). Focus groups yield qualitative results about consumer beliefs that are not achieved with consumer surveys (Tr. 2065-66). The purpose of this study was to explore consumers’ feelings and perceptions about dieting in general (Tr. 1564-65). Dr. Stewart testified that the focus group consumers did not take away from Fibre Trim commercials the health benefits claim (Tr. 2066, 2068), and Ms. McGee concluded that the target audience realized that Fibre Trim was not magical but was a sensible diet aid (Tr. 1567-68).

(2) Diet Concept Study (VOPAN Marketing Research)  
(January 1985)

78. From December 1984 to early 1985, Schering contracted with another independent market research firm, VOPAN, to conduct a qualitative study of Fibre Trim concepts for consumer advertising (RX 239; Tr. 1573-74, 1809, 2059). VOPAN stands for Voice Pitch Analysis, a sophisticated technique which measures two types of consumer response: (1) voice pitch changes; and (2) consumer recall of advertising messages (Tr. 1573-74, 1798-1800, 2059). The basic premise of this methodology is the belief that consumers' true feelings can be discerned from variations in the intonations in their voices (Tr. 1487, 1573, 1798-99).

79. The specific objective of the VOPAN study was to determine which one of four concepts for Fibre Trim was most persuasive and seemed to communicate the best information about the product (RX 192, p. 3; Tr. 1814).

80. VOPAN's methodology involved a mall intercept test of forcing exposure of one of the four concepts to 150 women who had dieted in the past year, who planned to diet in the future and who were 25-49 years of age (RX 192, p. 4; Tr. 1812).

81. The consumers reviewed one of four "concepts," rather than specific advertisements (Tr. 1814-15), which were developed by the advertising agency (Ogilvy & Mather), Schering and VOPAN (Tr. 1576).

82. According to Dr. Stewart and Ms. Fazio, the results of the VOPAN test do not indicate that consumers took away the message that Fibre Trim would provide specific health benefits associated with a fiber-rich diet or a high intake of dietary fiber from food (Tr. 1831, 2060, 2062). Ms. Fazio concluded that no data in this study indicated that the Fibre Trim positioning communicated to consumers that it is an effective appetite suppressant which works like Dexatrim (Tr. 1832; RX 192) or that Fibre Trim would produce weight loss without needing to cut back on calories (Tr. 1835).

83. Elements of all the concepts which tested favorably were incorporated into commercials and other Fibre Trim advertising (Tr. 1487, 2063-65).

(3) Mapes & Ross Television Commercial Testing  
(April and May 1985)

84. Prior to the formal test marketing of Fibre Trim (in April and early May 1985), Schering contracted with an independent market research firm, Mapes & Ross, to conduct consumer testing of three commercials -- "French Girls," "Sensible Girls," and "Take It Off" (a Canadian commercial) for consumer appeal and message communication, among other things (Tr. 1492-93, 1606, 1616; RX 243).

85. Ms. McGee of Schering testified that the Mapes & Ross consumer testing, including the verbatim consumer responses, do not indicate that people who saw the Fibre Trim commercials understood them to communicate that it was an effective appetite suppressant (Tr. 1620) or that taking fiber would provide the health benefits of a diet high in fiber from foods or that the people who saw the commercials understood them to suggest that taking Fibre Trim would provide any specific health benefits, like reducing the risk of colon cancer or coronary heart disease, or any other health benefits (Tr. 1619; RX 243, RX 262).

(4) Diet Product Awareness, Trial and Usage Study, Waves I and II  
(July and September 1985)

86. In September 1985, the marketing research firm, Total Research Corporation ("TRC"), conducted an Awareness Trial and Usage ("ATU") study at Schering's request to examine which television commercial, including "French Girls," was most effective in communicating the desired advertising message about Fibre Trim to consumers in the test markets and what spending level was necessary for the commercial to be effective (Tr. 1637-41, 1918; RX 246).

87. An ATU study is a survey intended, among other things, to measure the awareness that consumers have of a particular product or several products in the product category, and to determine how many people have tried the product and how many people continue to use the product (Tr. 1918). The ATU study also contained questions regarding consumers' sources of information about Fibre Trim and what messages they might have taken away from that source (Tr. 1933).

88. In Dr. Stewart's view, the ATU studies do not contain any data indicating that consumers took away from Fibre Trim

advertising the message that it will provide the health benefits associated with a fiber-rich diet or a high intake of dietary fiber from food because the responses to the ATU studies show that consumers did not mention any specific benefits of fiber (RX 224, RX 225; Tr. 2070-72). Furthermore, he concluded that the studies reveal that consumers carried away messages from the advertisements that Fibre Trim was sensible and natural and did not contain drugs or stimulants (Tr. 2069-70; RX 224).

(5) Diet Aid Repeat Purchase Study Tabulations (TRC)  
(December 1985)

89. In December 1985, TRC interviewed by telephone a sample of consumers who had purchased Fibre Trim and mailed back Business Reply Cards included in the Fibre Trim package (Tr. 1951, 1953; RX 226, RX 227). The results of the interviews were tabulated by TRC and provided to Schering (Tr. 1953; RX 227).

90. The questionnaire used for the interviews included the question "What, if anything do you particularly like about Fibre Trim? What else do you like?," which was posed to both current and non-current users of Fibre Trim (RX 226, pp. 3-4; Tr. 1951, 1954). Mr. Leury of TRC testified that no consumers responded that they thought they were getting a specific health benefit such as reduced risk of colon cancer or reduced risk of diabetes when asked this question (Tr. 1954-55; RX 227, p. 23).

(6) "Fibre Trim User Study" (TRC) (October 1986)

91. In September 1986, TRC conducted another study, entitled "Fibre Trim User Study," based on the results of telephone interviews with a sample of 200 consumers who had purchased Fibre Trim and returned Business Reply Cards (Tr. 1958, 2072-73; RX 228).

92. Dr. Stewart testified that the Fibre Trim User Study indicates that Fibre Trim advertising did not communicate to consumers the message that Fibre Trim provides the health benefits associated with a fiber-rich diet or a high intake of dietary fiber from food (RX 224, RX 225, RX 228; Tr. 1969-71, 2073), and Mr. Leury stated that the advertising did not communicate to the consumers the message that Fibre Trim is an appetite suppressant like Dexatrim (Tr. 1969-71; RX 224, RX 225, RX 228).

(7) Gallup and Robinson Copytesting of the Print Advertisement "French Resistance" (July 1986)

93. Gallup and Robinson, a marketing research company, copytested the "French Resistance" print advertisement which appeared in the Ladies Home Journal in July 1986, and prepared a "Full Ad Impact Report" on its findings (Tr. 1667; RX 260).

94. Consumer researchers interviewed consumers and examined the messages they recalled from "French Resistance" 24 hours after seeing it in the magazine (RX 260; Tr. 2054). The report showed that the "French Resistance" print advertisement was effective in registering the name of the product to the consumer and communicated the main idea in the advertisement, but Ms. McGee concluded that none of the verbatim responses in the copy test indicate that consumers believed from the "French Resistance" advertisement that taking Fibre Trim would provide them with the health benefits associated with a diet high in fiber from food and that none of the verbatim consumer responses from copytesting showed that consumers took away from "French Resistance" the message that Fibre Trim would provide a particular health benefit, like decreased risk of colon cancer or coronary health disease, diabetes, or any other specific health benefit (Tr. 1670; RX 260, pp. 10-14). None of the verbatim responses indicated that consumers saw a message that Fibre Trim is an effective appetite suppressant like Dexatrim (Tr. 1670; RX 268, pp. 10-14).

(8) Research Systems Corporation Copytesting of the Television Commercial "Enfant Terrible" (1987)

95. In 1987, Research Systems Corporation, an independent marketing research company, copytested the commercial "Enfant Terrible." The testing methodology involved exposing consumers to the commercial in an auditorium format (Tr. 1678-79; RX 350).

96. According to Ms. McGee, the verbatim responses of the study did not indicate that consumers who saw the "Enfant Terrible" commercial understood it to suggest that Fibre Trim was an effective appetite suppressant or that it provides the health benefits from foods high in fiber. None of the verbatim comments from the study indicated that consumers understood from the "Enfant Terrible" commercial that taking Fibre Trim provides any specific health

benefit like decreased risk of colon cancer, coronary heart disease, or any other specific health benefits (Tr. 1680; RX 350, pp. 31-38).

(9) Gallup and Robinson - Magazine Impact Research Service  
Full Ad Impact Report on the Print Advertisement  
"Test of Time" (March 1987)

97. Gallup and Robinson's Magazine Impact Research Service copytested the print advertisement "Test of Time" as it appeared in Cosmopolitan magazine in March 1987 and prepared a "Full Ad Impact Report" on its findings. The objective of the report was to measure various consumer responses such as proven name registration, idea communication, and favorable buying attitude (persuasion) (Tr. 1683-84; RX 261).

98. Ms. McGee's testimony regarding the message of this advertisement was similar to that given with respect to the "Enfant Terrible" advertisement (Tr. 1686).

(10) Diet Products Market Structure Study (TRC) (March 1987)

99. TRC conducted a study, the final report of which was entitled "Diet Products Market Structure Study Presentation and Final Report," dated March 1987 (RX 229; Tr. 1971, 2074).

100. A market structure study is a comprehensive study of the structure of a market in which a product competes, with the objective of identifying consumers' perceptions about each product relative to other products, the particular attributes that differentiate products within a particular product market and those consumers with different needs and interests (Tr. 1919-20, 2075).

101. The objectives of the Fibre Trim market structure study were, among other things: (1) to understand the market for diet aid products so that Schering could identify groups or subgroups of consumers to whom Schering might best target or promote Fibre Trim; (2) to understand the competitive structure to identify any gaps or niches in the market; and (3) to determine the best positioning for Fibre Trim in the market (Tr. 1973-74; RX 229, p. 4).

102. The market structure study used a national probability sample approach that would be representative of the population of people on a diet in the past year who were between the ages of 18 and 54. A questionnaire was mailed to 811 qualified respondents, and a

high rate of two-thirds of the people responded (Tr. 1975-76). The questionnaire asked a battery of questions about dieting and diet products, such as questions about awareness and usage of diet products, prospective use of diet products, the importance of various attributes of a diet product or method, evaluation of 11 specific diet products, the importance of exercise to lose weight, and descriptions about themselves (Tr. 1979-80; RX 229, pp. 74-92). The market structure study assessed consumers' perceptions of the entire diet category, including Fibre Trim, diet pills such as Dexatrim, weight loss programs, lower calorie products, exercise, and other products in the diet category (Tr. 2053).

103. Dr. Stewart's analysis of this study led him to conclude that there was no data that suggests that consumers took away from Fibre Trim advertising the message that it will provide the health benefits associated with a fiber-rich diet or a high intake of dietary fiber from food (Tr. 2076; RX 229), and Mr. Leury testified that consumers differentiated Fibre Trim from PPA and products like Dexatrim and Accutrim (Tr. 1982, 1988-90; RX 229, p. 19). He also concluded that consumers understand that cutting back on food is necessary when one is on a diet (Tr. 1985).

(11) Additional Focus Group Testing (June 1987)

104. In June 1987, Marketing Perceptions, Inc., conducted additional focus group consumer research regarding Fibre Trim (Tr. 1688-89; RX 251, RX 267). The focus group testing involved conducting eight focus groups of consumers in Stamford, Connecticut fitting Schering's description of the target audience, *i.e.*, women from ages 25 to 45, who had dieted in the past and who were between 5 and 20 pounds over their desired weight (Tr. 1691; RX 251).

105. The focus groups extensively discussed the "French Girls" television commercial and Ms. McGee testified that consumers perceived from this advertisement that Fibre Trim is unique because it is all natural (Tr. 1692-93; RX 251, RX 267, p. 2). The study also showed to Ms. McGee that consumers realized that if Fibre Trim did not work it was because they failed to cut back on calories and did not exercise (Tr. 1692-93).

(12) Ross-Cooper Associates "Pills" Advertisement  
Communication Test (February 1988)

106. Schering requested Ross-Cooper Associates ("Ross-Cooper"), an independent marketing research firm, to conduct and design a communications study on the "Pills" advertisement in 1988 (Tr. 1871-73; RX 313). The purpose of the Ross-Cooper copy test was to determine what messages consumers took away from the "Pills" advertisement (Tr. 1867, 1872).

107. Schering informed Ross-Cooper what qualifications respondents needed to satisfy before they should be selected to participate in the test. These specified characteristics fit the description of the intended target audience for Fibre Trim (Tr. 1874).

108. The "Pills" communications study involved face-to-face interviews with respondents chosen in central location facilities, such as a shopping mall (Tr. 1872-75).

109. The "Pills" advertisement questionnaire contained open-ended questions which explored: (1) the main idea communicated by the advertisement; (2) other ideas in addition to the main one communicated by the advertisement; (3) product advantages; (4) product disadvantages; (5) how a respondent would describe the advertised product to a friend; (6) anything respondents found confusing about the advertisement; (7) whether or not respondents agreed with the advertising copy; and, if not, what specifically they disagreed with (Tr. 1878; RX 213, pp. 53-54).

110. Respondents were also asked closed questions asking them: (1) to select as many words which best described the advertisement; (2) interest in purchasing Fibre Trim; (3) whether they found the product to be unique; and (4) whether they agreed or disagreed that the advertisement made certain statements (Tr. 1878-79). The "Pills" advertisement communications test was validated according to industry standards (Tr. 1876).

111. The "Pills" study showed that, after the second exposure to the advertisement, respondents understood the main ideas communicated to be that Fibre Trim is an all-natural product, that it contains fiber, that it is safe and sensible, and that it does not contain drugs (RX 213; Tr. 1879, 1887, 2052-53, 2058).

112. Mr. Kweskin of Ross-Cooper testified that the "Pills" advertisement did not communicate to consumers that Fibre Trim has chemicals and works to suppress appetite or that it provides the health benefits of a high fiber or fiber-rich diet (Tr. 1889-90; RX 213,

RX 216) and Dr. Stewart pointed to the fact that consumers did not mention specific benefits of fiber (Tr. 2058; RX 213).

113. Since the "Pills" advertisement contained elements which have been incorporated into other Fibre Trim advertisements, Dr. Stewart believes it is possible to generalize from the results of this communication test to other Fibre Trim advertisements to the extent they contain common elements, *i.e.*, that Fibre Trim is natural, is made of fiber, contains no drugs, and fills one up (Tr. 2058).

*e. The Probative Value of Schering's Research*

114. Many of the studies relied upon by Dr. Stewart and other witnesses did not test advertisements which were actually disseminated to the public: For example, the VOPAN study analyzed consumer reactions to four advertising concepts (Tr. 1573, 1814-15; RX 192) which are uncreative descriptions of a product (Tr. 1577-78). The concepts tested by VOPAN made no reference to the health benefits of the fiber in Fibre Trim (Tr. 1844-45, 2142-43) and neither Ms. Fazio of VOPAN nor Dr. Stewart compared the results of this study with any specific Fibre Trim advertisement (Tr. 1843, 2063-64).

115. In fact, neither of these witnesses could conclude from this study that advertisements like "Shape of Europe" ("Fibre Trim even offers you all of fiber's wonderful health benefits") (CX 295, CX 297) did not convey the health benefits claim (Tr. 1844-45, 2143). (*See also* Tr. 1845-46 re CX 279.) Since the Fibre Trim advertisements contain specific language discussing the health benefits of Fibre Trim, the concepts tested by VOPAN, which made no reference to such language, reveal nothing useful about any actual Fibre Trim advertisements. The same defect exists in focus group studies, for their results are not applicable to the language of the advertisements in question (*see* Tr. 1764).

116. The absence of responses mentioning the health benefits of fiber in the TRC studies was relied upon by Mr. Levine of that company and Dr. Stewart as support for their perception that the Fibre Trim advertisements conveyed no health benefit claims (Tr. 1968-69, 2070-73, 2078), but both gentlemen conceded that the results of the July and September 1985 study could not be connected with specific Fibre Trim advertisements that were disseminated during this time period (Tr. 2004, 2131). This is contrary to the

concept that consumer surveys which measure communication should expose respondents to the advertisements being tested (*see* Tr. 2129).

117. TRC also conducted telephone repeat purchase user surveys which asked current and former Fibre Trim users what they liked and disliked about it, but they contained no questions regarding Fibre Trim advertising (Tr. 1951-52, 1960-61; RX 226, RX 227, RX 228); therefore, whatever responses were given are not probative because they do not relate to the issue of the health benefits claim (*see* Tr. 2007, 2012, 2138).

118. The object of TRC's diet products market study was not to discover the messages which Fibre Trim advertisements conveyed to consumers (*see* Tr. 1973-74). Consumers were not shown any Fibre Trim advertisement or asked if they had ever seen one (Tr. 2014-15, 2139); thus, the absence of responses relating to the health benefits claim is not surprising and does not, as Dr. Stewart claimed (Tr. 2076), reveal anything useful about the health benefits issue (*see* Tr. 2018, 2139-40).

119. Complaint counsel stipulated that the "Pills" advertisement which was studied in the Ross-Cooper mall intercept survey (Tr. 1870-73; RX 213, RX 394) makes no representations about the health benefits of fiber or Fibre Trim (Tr. 2055, 2057).

120. Nevertheless, Dr. Stewart relied on this advertisement insofar as it contains elements which appear in other Fibre Trim advertisements (Tr. 2058-59), but I reject the claim that this advertisement has some probative value with respect to advertisements which refer to health benefits. For example, the language "Fibre Trim even offers you all of fiber's wonderful health benefits as well" is contained in CX 295, a version of the "Shape of Europe" advertisement. Dr. Stewart admitted that, because this language was not contained in the "Pills" advertisement, he could not conclude, based upon the results of RX 213, that CX 295 did not communicate the health benefits claim to reasonable consumers (Tr. 2153-54).

121. Schering claims that copy tests of the advertisements "Sensible Girls," "French Girls," "Take It Off," "French Resistance," "Enfant Terrible," and "Test of Time" establish that the health benefits claim was not made. Like the "Pills" advertisement, these are not alleged to make that claim, and copy tests analyzing their message reveal nothing about the messages conveyed by the challenged advertisements.

122. Because the studies relied on by Dr. Stewart and other witnesses have no clear connection with the advertisements conveying the Fibre Trim health benefits claim, I reject his, and Schering's, conclusion that their results are useful in determining the messages conveyed by the advertisements in question.

## 2. The Weight Loss and Weight Maintenance Claims

123. Schering admits, as the complaint alleges, that the challenged advertisements represented, *inter alia*, that Fibre Trim is an effective weight loss, weight control, or weight maintenance product (Cplt, paragraph 10; Ans., paragraph 10; Tr. 86-87).

## 3. Modifications of the Weight Loss and Weight Maintenance Claims

### *a. The Advertisements*

124. Many consumers realize that diet and exercise are an essential part of a weight loss program (Tr. 282), and several Schering witnesses testified that the Fibre Trim advertising campaign did not present it as a panacea or magic solution to weight problems and stressed the consumers' responsibility to eat right, cut back on calories and exercise more (Tr. 97, 113, 117, 1622-23, 2056-57). Some Fibre Trim advertising incorporated these concepts:

Fibre Trim isn't magic, but it is a sensible, gradual aid to weight loss. If you take Fibre Trim before meals, eat sensibly and get more exercise, you should begin to notice results (RX 351; CX 279, CX 292, CX 295; *see also* RX 355; CX 287).

It's no panacea -- just natural help that makes eating less a little more bearable (RX 395; CX 285).

Eat right. Eat less. Move around more. With Fibre Trim, a tough job becomes much easier (CX 299; RX 397; Tr. 1622; *see also* CX 297 (containing nearly identical language)).

The Fibre Trim plan means eating less, eating right, moving around more, and gradually losing that extra weight (CX 285; RX 395; Tr. 1661).

By eating healthier food, a little less food, and moving around more. And that's precisely the Fibre Trim way: FIBRE TRIM VS. A STIFF UPPER LIP. Eating less is simple in theory. And with Fibre Trim, equally simple in practice (CX 286; RX 398; Tr. 1663-64).

Take Fibre Trim, stick with a reasonable diet, move around more, and be patient (CX 287; RX 355).

With help from Fibre Trim, you won't have to give up all those wonderful holiday treats. You'll simply eat less of them. The Fibre Trim approach means eating less, moving around more and losing weight gradually (RX 396; Tr. 1664-65).

If you make [Fibre Trim] part of a sensible diet plan, one that includes exercise and eating the right foods, Fibre Trim will help you lose weight . . . (RX 394; CX 294).

Sensible, So Sensible. But let's face it. You can't eat cheesecake for breakfast, lunch and dinner, and lose any weight. Anyone who's ever dieted knows the basics. Eat right. Eat less. And move around more. It's not easy. But Fibre Trim will surely help make it easier (CX 296; RX 397; Tr. 1624-25; *see also* RX 357; CX 295 (containing nearly identical text)).

125. These admonitions amount to little more than general statements about the desirability of maintaining a healthy life style.

126. In fact, the audio portion of these advertisements conveys the impression that using Fibre Trim will result in reduced calorie intake without the need to consciously adhere to a reduced calorie diet:

Now I'm taking it [weight] off and helping to keep it off . . . I take Fibre Trim natural source fiber tablets as directed. They help me to enjoy smaller portions of good food without feeling hungry (CX 340, CX 343).

Your mother is so beautiful, so slim. Does she eat? Silly, just not so much with this--Fibre Trim. . . (CX 339, CX 343).

Eat? She can't possibly eat. Yes, just not so much. With Fibre Trim (CX 341, CX 343).

She can't eat nothing. Her ladyship simply eats a bit less . . . with Fibre Trim (CX 342, CX 343).

Your mother fits into this? How? She eats a little less with Fibre Trim (RX 350, p. 45; CX 343).

127. None of Schering's Fibre Trim television advertisements contain any audio language that states or implies that consumers need consciously adhere to a reduced calorie diet while taking Fibre Trim in order for Fibre Trim to be efficacious as a weight loss or weight maintenance product (Tr. 1523-24, 1705-06, 2864-65; *see* CX 339, CX 340, CX 341, CX 342, CX 343, CX 344).

128. The superscript (words superimposed over the visual image, Tr. 2123) of some television advertisements states "part of [or "with"] a sensible diet plan" (*see* CX 339, CX 341, CX 342, CX 343, CX 344), while in others it states "use as directed" (CX 340). The superscripts are, however, difficult to read, are briefly displayed and are not accompanied by an audio voice over (*see* CX 339, CX 340, CX 342, CX 343, CX 344). Because their language is vague and

their legibility is limited, these superscripts do not convey to reasonable consumers that they must consciously adhere to a reduced calorie diet for Fibre Trim to be effective.

129. Many of the Fibre Trim print advertisements do not mention reducing caloric intake (*e.g.*, CX 271, CX 272, CX 273, CX 274, CX 278, CX 281, CX 283, CX 293, CX 298, CX 347, CX 348, CX 350, CX 351, CX 352, CX 353, CX 355, CX 356, CX 357, CX 358, CX 359, CX 377, CX 387), and Schering employees who were responsible for internally reviewing Fibre Trim copy (Tr. 1519, 1522, 2536) agreed that certain advertisements stated that Fibre Trim made one want to eat less and did not mention the need to follow a reduced calorie diet (Tr. 2548 *re* CX 296; 2548 *re* CX 387. *See* CX 463, p. 1; Tr. 2373).

130. Some print advertisements state that while taking Fibre Trim the consumer can “eat real food, normal food” (CX 296), “enjoy the good foods you like” (CX 280; *see* CX 279, CX 292), or “still eat normally” (CX 295). These statements leave consumers with the net impression that they do not need to consciously change their food consumption habits while taking Fibre Trim.

131. Other language in the Fibre Trim advertisements implies that it will help them to lose weight by causing them to eat less.

Taken with water before meals, Fibre Trim gives you a pleasant feeling of fullness. So you can still eat real food, normal food--but eat less without feeling starved (CX 296).

Its [Fibre Trim’s] concentrated fiber lets you enjoy the good foods you like, while feeling satisfied with smaller portions (CX 280).

132. Admonitions in these advertisements stating that “[y]ou can’t eat cheesecake for breakfast, lunch and dinner, and lose any weight. . . . Eat right. Eat less. And move around more” (CX 296) and “[s]o eat smaller portions, consume fewer high calorie drinks, and increase your fiber intake” (CX 280), do not warn reasonable consumers that they must consciously adhere to a reduced calorie diet if Fibre Trim is to be an effective weight loss product, especially since they are preceded by the language quoted just above which suggests that Fibre Trim itself can reduce caloric intake and that no further caloric reduction is needed to lose weight.

133. Dr. Shimp, who has testified in two federal court proceedings regarding the claims that advertisements were likely to convey to reasonable consumers (Tr. 69-71), concluded after reviewing the

Fibre Trim advertisements that they did not convey to reasonable consumers that conscious adherence to a reduced calorie diet was required if Fibre Trim was to be an effective weight loss and weight maintenance product (Television advertisements: Tr. 94 *re* CX 340; 96, 97-101 *re* CX 339; CX 341, CX 342, CX 343); (Print advertisements: Tr. 102-05, 118, 121-22, 141-42 *re* CX 271, CX 272, CX 273, CX 278, CX 293, CX 377, CX 387).

134. Dr. Shimp conceded that some television and print advertisements contain references to diet or reducing plans (*see* CX 340 "Fibre Trim Reducing Plan" and superscript "use as directed"; CX 341, CX 342, CX 343 superscript "part of a sensible diet plan"; CX 279, CX 285, CX 286, CX 287, CX 292, CX 295, CX 296, CX 297, CX 299: "Eat right. Eat less. Move around more"), but he concluded that the print language, and the television superscripts were vague and ambiguous and did not tell consumers that Fibre Trim is effective only if used in conjunction with a reduced calorie diet (Tr. 94-106).

135. Dr. Shimp's dismissal of the superscripts was echoed by Dr. Stewart, Schering's expert in consumer information processing. He testified that marketing research, including his own research, demonstrates that superscripts that do not reinforce the primary message of a TV commercial tend either to be ignored by or confuse the viewer (Tr. 2123).

136. A few of Schering's advertisements contained somewhat more specific language regarding adherence to a diet while taking Fibre Trim (Tr. 112-15, 126-27, 131-32). However, none of these advertisements -- "Pills" (CX 294), the "Fiber Facts" brochure (CX 275), or the package insert (CX 280) -- according to Dr. Shimp, represent to reasonable consumers that Fibre Trim will only be an effective weight loss and maintenance product if the consumer consciously follows a reduced calorie diet (Tr. 112-13, 115, 126-27, 131-32) since the language in both the full page and half page versions of the advertisement entitled "Pills" (CX 294) does not inform the consumer that a reduced calorie diet is necessary for Fibre Trim to be efficacious, it does not provide a specific plan for dietary behavioral change, and it is ambiguous with regard to any recommended behavioral changes (Tr. 112-13, 115).

137. CX 275, the eight-page point of purchase brochure called "Fiber Facts," states on one of its pages that in order to lose weight one should reduce caloric intake and increase exercise (CX 275; Tr. 126), but Dr. Shimp concluded that this statement is "a trivial part"

of the brochure and accordingly would not be understood by reasonable consumers as a representation that Fibre Trim will not be efficacious unless consumers consciously follow a reduced calorie diet and increase their exercise level (Tr. 127). To the contrary, this brochure contains language, such as "Fibre Trim works to satisfy you naturally and keeps you satisfied so you eat less," that represents that Fibre Trim by itself satiates one in a fashion that makes one eat less, thereby causing the recommended reduction in caloric intake and the resulting weight loss (Tr. 127-28).

138. While the second page of the Fibre Trim package insert, CX 280, contains some general recommendations regarding changing eating habits and increasing exercise to lose weight, Dr. Shimp concluded that these would not be interpreted by reasonable consumers as an assertion that Fibre Trim only works if the consumer undertakes those suggested behavioral modifications. In fact, CX 280 represents to reasonable consumers that using Fibre Trim itself will cause them to feel fuller, reduce their desire to eat and cause weight loss (Tr. 131, 132).

*b. Conclusion*

139. Schering points to consumer research which it commissioned as establishing that its advertisements informed reasonable consumers that Fibre Trim was effective only if used along with a reduced calorie diet (RPF's 84, 101, 172, 179).

140. Two of these studies reported the results of focus groups (CX 311; RX 235), but none of the participants in the 1984 study were shown advertisements that were disseminated to consumers in the United States (*see* Tr. 1764), and the Schering employee who attended the 1987 focus group could not recall what, if any, advertising copy was shown to participants (Tr. 1708-09).

141. The VOPAN study (RPF 101) tested advertising concepts, not advertisements that were actually disseminated and its probative value with respect to actual advertisements is unclear. The same problem exists with respect to TRC's diet products market structure study (RPF 172).

142. Furthermore, neither the VOPAN nor TRC studies directly asked respondents whether the tested concepts or advertisements conveyed to them the message that Fibre Trim was efficacious only if it were taken in conjunction with a reduced calorie diet.

143. Although Schering's advertisements were directed at up-scale women who might be skeptical about advertising claims, a Schering document estimated that 70% of its 1986 sales of Fibre Trim were to consumers "looking for the magic pill" and who "want a product that will do the work" (CX 465, pp. 2, 6). This confirms complaint counsel's claim that Schering's advertisements were designed to emphasize that using Fibre Trim itself would result in weight loss. The admonitions about dieting, when they were included in advertisements, were not intended to detract from this message.

144. Thus, its advertisements, which Schering admits made the weight loss and weight maintenance claims, did not convey to reasonable consumers the message that they must adhere to a reduced calorie diet if Fibre Trim were to be effective. In fact, the appetite suppressant claims which were contained in many of the advertisements suggested just the opposite: that the feeling of fullness caused by Fibre Trim accomplishes the same result as, and obviates the need for, a diet.

#### 4. The Appetite Suppressant Claim

145. Schering's marketing strategy intended to convey the message that Fibre Trim was not a drug and that it was different from the other "quick-fix" dieting methods such as appetite suppressants like Dexatrim and Acutrim and meal replacement products such as Slimfast (Tr. 1587; RX 240, pp. 5, 7).

146. This marketing strategy was carried out in advertisements which stressed that Fibre Trim is a natural food, not a drug (Tr. 114, 124-25, 128-30, 20, 56-57) and is an all-natural, safe and sensible product (Tr. 94, 111-112, 114, 128, 1624-27, 1658, 1678, 1682-83).

147. However, while the Fibre Trim advertisements differentiated it from appetite-suppressant drugs, they also conveyed to consumers the impression that it, like those drugs, suppressed one's appetite (*see* CX 273, CX 275, CX 279, CX 280, CX 285, CX 286, CX 287, CX 292, CX 294, CX 295t CX 296, CX 297, CX 299, CX 340, CX 347, CX 348, CX 349, CX 351, CX 354, CX 355, CX 357, CX 358, CX 359, CX 387).

148. The following language, taken from Fibre Trim advertisements, illustrates the claims made with respect to its effect on appetite:

1. "Taken with water before meals, Fibre Trim gives you a pleasant feeling of fullness. So you can still eat real food, normal food -- but eat less without feeling starved" (CX 296).
2. Fibre Trim tablets "help me to enjoy smaller portions of good food without feeling hungry" (CX 340).
3. Fibre Trim "makes you feel satisfied with less food" (CX 387).
4. Fibre Trim lets you "eat less without feeling famished (or "hungry")" (CX 286, CX 287).
5. Fibre Trim "promotes satiety" [or "satiates"] (CX 266, CX 357).
6. Fibre Trim provides a "pleasant feeling of fullness" (CX 347), is a "hunger deterrent" (CX 354), "fights off those hunger pangs" (CX 297), "takes the edge off hunger" (CX 280) and "helps you control your appetite" (CX 294).

149. This language allows only one interpretation: That although Schering intended to differentiate Fibre Trim from appetite-suppressant drugs and their undesirable side effects, its advertisements convey to reasonable consumers the net impression that Fibre Trim is an effective appetite suppressant.

150. Dr. Shimp's testimony supports my conclusion that most of Schering's advertisements make the appetite suppressant claim (Tr. 85, 91, 107, 111, 113-14, 117-18, 119, 128, 132, 136, 138, 140 and 147). Furthermore, Ms. McGee, senior brand manager for Fibre Trim, testified that in a survey of Fibre Trim users asking them what they liked about the product, the second most frequently given response was that "it reduces appetite" (Tr. 1674; RX 265, p. 13). Finally, a copy test of the "Pills" advertisement revealed that many of those surveyed understood the advertisement to claim that Fibre Trim curbs appetite (RX 213, pp. 20, 44). If, as Schering claims, these analyses reveal consumer attitudes toward Fibre Trim, it knew or should have known that its advertisements conveyed the appetite suppressant claim.

151. Schering research which purportedly shows that consumers perceived Fibre Trim as different from appetite suppressant drugs like Dexatrim reveals nothing about the appetite suppressant message which specific language in the advertisements conveys, for the intent of the advertisements was to emphasize Fibre Trim's natural ingredients, not to disclaim its appetite suppressant effects.

## 5. The High Fiber Supplement Claim

152. Schering admits the allegation that its advertisements represented that Fibre Trim is a high fiber supplement (Cplt, paragraph 6, Ans., paragraph 6).

## 6. The Daily Requirements Claim

153. Subparagraph 2 of paragraph six of the complaint alleges that Schering's advertisements represented that the recommended daily dosage of Fibre Trim provides most of a person's daily requirements of dietary fiber ("daily requirements claim").

154. The Fibre Trim package insert (CX 280) recommends that consumers "use Fibre Trim as a daily dietary fiber supplement" and states that Fibre Trim "is a superior source of dietary fiber" (CX 280, p. 1). The "Fiber Facts" brochure claims that Fibre Trim is a superior source of dietary fiber and warns that consumers need "to have plenty of fiber" (CX 275, p. 2). (*See also* CX 310, p. 11.)

155. Many Fibre Trim advertisements refer to it as a high fiber supplement or state that it may be used as a fiber supplement (CX 271, CX 281, CX 282, CX 283, CX 350, CX 352, CX 353, CX 354, CX 357, CX 358, CX 359).

156. While Fibre Trim advertisements and product inserts refer to it as a fiber supplement, they do not explicitly state that the recommended daily dosage of Fibre Trim provides most of a person's daily requirements of dietary fiber and I cannot infer with any confidence that consumers take away from this language a belief that Fibre Trim's fiber content is so high that it provides all of their daily requirements of fiber, and I reject as speculative Dr. Levy's opinion as to the message this language conveys to consumers (Tr. 265, 276-79).

## 7. The Fiber Content Claim

157. Subparagraph 3 of paragraph six alleges that Schering advertisements and promotional materials represent that the recommended dosage of Fibre Trim provides about 2.35 grams of dietary fiber per serving or about seven grams of dietary fiber per day (Cplt, paragraph 6). Schering admits this allegation (Ans., paragraph 6).

*F. Substantiation For The Weight Loss, Weight Maintenance,  
And Appetite Suppression Claims*

1. Introduction

158. Several Schering advertisements and promotional materials expressly or impliedly assert that the claims discussed above are scientifically supported:

Fibre Trim was developed by scientists in Scandinavia (CX 275).

In a controlled study. . . . In two additional studies, weight loss with Fibre Trim was confirmed (CX 354).

Proven successful (*e.g.*, CX 287, CX 295, CX 346). Fibre Trim works (*e.g.*, CX 280). Developed by a distinguished group of nutrition experts (CX 292).

159. Experts testifying in this case agreed that if Schering claimed scientific substantiation, at least two well-conducted and controlled clinical trials were needed to establish Fibre Trim's efficacy (Tr. 785, 944, 2686, 2832, 3100, 3792). The cost of conducting two such trials should not exceed \$400,000 (Tr. 1096).

2. The Requirements For Well-Designed Clinical Trials

*a. Undisputed Requirements*

160. The experts testifying for the parties agreed on the essential elements of clinical trials which are designed to evaluate the efficacy of a weight-loss product:

1). A pre-study protocol should be devised which sets forth how the research is to be implemented and analyzed, including how subjects are to be randomized into treatment groups, and what statistical techniques are to be employed (Tr. 3040).

2). The product should be tested against a placebo, which controls for the effect which test subjects often experience simply because they are being treated. A placebo helps control for the subjective reactions of the subject and subjective input from the investigator (Tr. 2684).

Ideally, a placebo should have the same appearance as the active ingredient being tested so that neither the investigator nor the subject knows whether the active ingredient or the placebo is being administered (Tr. 783, 960, 2684, 3314-15). The placebo effect is experienced in both the placebo and active groups because both groups believe that the treatment will be effective (Tr. 2937-38).

3). Subjects should be assigned to the treatment and placebo groups by randomization, a procedure which assures that each has an equal probability of

being assigned to one of the two groups. Randomization eliminates assignment bias, *i.e.*, prejudice that might occur if the investigator were allowed to decide to what group subjects are assigned (Tr. 2602, 3229, 3546).

4). Double blinding minimizes bias by withholding knowledge of placebo or treatment group assignments from the subject and the investigator. Double blinding is especially important when subjective measurements are made, for if the investigator knows to which group the subject is assigned, his perception of the treatment's effects may be altered by that knowledge (Tr. 2605, 2680-81, 3229, 3546).

5). It is generally agreed that a treatment's efficacy should be tested in clinical trials conducted by independent investigators, for one investigator's commitment to the hypothesis being tested may influence his perceptions of a study's results. Confirmation by independent research is, therefore, desirable (Tr. 785, 944, 2451, 2453, 3792).

6). Peer review and publication in a reputable scientific journal validates a study's worth (Tr. 786, 946-47, 3791).

#### *b. Disputed Requirements*

161. There is some dispute between the experts as to other requirements for clinical trials:

1). The intention-to-treat principle requires that all subjects that have been randomized into a study must be included in its statistical analysis since anything which occurs post-randomization may be related to the treatment (Tr. 2612-13, 2922, 3227, 3556, 3666; RX 195, pp. 2-3). This principle is designed to eliminate the potential for bias that may result if researchers are allowed to select data which they consider "valuable for efficacy" (Tr. 2613-17, 2716-17). Every clinical trial submitted to the FDA must include an intention-to-treat analysis (Tr. 2613).

2). Most of the Fibre Trim studies distinguished between subjects who discontinued a trial for reasons related to the treatment given (withdrawals) and those who discontinued for reasons not related to the treatment (dropouts) (Tr. 2927-29, 3230-31, 3679).

Withdrawals were assigned the highest observed weight as the final weight measurement; dropouts were assigned the last weight observed as the final weight measurement (Tr. 2981-83, 3230-31, 3679-80). Studies submitted to the FDA routinely treat dropouts and withdrawals differently within the same study for purposes of data analysis (Tr. 2713).

3). When a study shows statistically significant results, it suggests that the observed differences between the placebo and the treatment groups did not occur by chance, but were the result of the treatment (Tr. 2623, 3547).

The conventional test of statistical significance accepts a "p value" of less than .05 -- *i.e.*, a result whose likelihood of occurrence by chance is less than five percent, or five times in one hundred occurrences (Tr. 969-71, 1038-39). P values of more than .05 are generally not accepted as indications of an actual difference between placebo and control groups.

P values can be calculated using “one tailed” or “two tailed” tests. A one tailed test tests the hypothesis that the active treatment is more effective than the placebo. A two tailed test tests the hypothesis that the active treatment may be more or less efficacious than the placebo.

Since the purpose of the clinical trials in question was not to test the latter hypothesis, the appropriate measure of statistical significance is one tailed (Tr. 2625-30, 2931-32, 3223-24, 3565-67). In fact, statistical “power,” *i.e.*, the ability of a test to detect an effect, is increased by the use of a one tailed test (Tr. 3223-24).

4). In each of the placebo-controlled tests discussed below, the placebo tablets contained more calories -- 35 to 60 -- than the Fibre Trim tablets to which they were compared (*e.g.*, Tr. 793, 820, 825), and complaint counsel’s experts claimed that this defect compromised the results of the trials because giving additional calories to the placebo subjects handicapped their ability to lose weight and biased the results in favor of the group which took Fibre Trim (Tr. 793-94, 961).

On the other hand, respondent’s experts testified that a 50 calorie difference is within the range of normal variance in daily food intake for persons adhering to a 1200 calorie diet and that it is not necessary to adjust the trial results to account for this difference (Tr. 2317-18, 2725, 3083, 3574-76, 3648).

### 3. The Clinical Trials Relied On By Schering Before Dissemination of the Challenged Weight Loss Advertisements

162. At the time it disseminated the Fibre Trim advertisements, Schering possessed and relied upon the Solum I, Rytting, and Hessel reports provided by Farma Food and described below (Tr. 2204-05, 2427-28, 2793-94; CX 333, pp. 17-19).

#### *a. SOLUM I: “Fibre Tablets, DumoVital, as a Means to Achieve Weight Reduction”*

163. This study was conducted in Norway by Toril Solum, a nurse specialist, and was published in The Journal of the Norwegian Medical Association in 1983 (RX 317, p. 1). Its purpose was to test the effect of Fibre Trim and diet on weight loss. It was a randomized, placebo-controlled, double-blinded study involving 53 subjects who came from a slimming club (RX 194, p. 4, RX 197, pp. 10, 17-21, RX 317, pp. 2-4, RX 321, pp. 3-6; Tr. 2644-45, 2972-75, 3256-57).

164. Each of the subjects was told to follow a 1100-1200 calorie diet with an estimated content of approximately 30 grams of dietary fiber. Thirty subjects received 16 Fibre Trim tablets per day; 23 subjects received a corresponding number of placebo tablets (RX 32, pp. 3-6, RX 194, p. 4, RX 197, pp. 10, 17-21, RX 317, p. 2; Tr. 2644-45, 2972-75, 3256-57).

*b. RYTTIG: "Treatment of Slightly to Moderately Overweight Persons"*

165. The Rytzig study was conducted in Copenhagen, Denmark, by Kjeld Rytzig (principal investigator), Laila Haegh, and Stig Larsen, and was published in *The Journal of the Norwegian Medical Association* in 1984 (RX 324, p. 1). Its purpose was to test whether Fibre Trim tablets, when taken in conjunction with a reduced calorie diet, are an effective aid to weight reduction (RX 324, p. 2, RX 327, p. 4).

166. The Rytzig study was randomized, placebo-controlled and double-blinded, and involved 90 slightly to moderately overweight subjects (RX 324, p. 2, RX 327, p. 4). Each subject was told to follow a 1200 calorie diet for an 11-week period (RX 324, p. 2, RX 327, p. 4). Forty-five subjects were given seven Fibre Trim tablets, four times a day, 30 minutes before meals, and 45 placebo subjects were given a corresponding number of placebo tablets (RX 324, p. 2, RX 327, p. 4).

*c. HESSEL: "Weight Reduction and Long-Term Weight Management of 41 Overweight Patients Using High Fibre Tablets as an Aid to Reduction of Caloric Intake"*

167. This was an open, retrospective study conducted by Lasse Hessel in Scandinavia and presented to The IV International Congress on Obesity in 1983 (RX 343, RX 344). Forty-one subjects were treated for overweight through dietary guidance and the use of Fibre Trim tablets (RX 197, pp. 6-7, RX 343, p. 4, RX 344, p. 2). The subjects were directed to take 6-8 tablets 30 minutes before each meal (18 - 24 tablets per day) (RX 197, pp. 7, 18, RX 343, p. 4, RX 344, p. 2). The average length of treatment was 136 days (RX 197, p. 7, RX 343, p. 4).

168. Twenty-four subjects who participated in the original Hessel study continued to use Fibre Trim for five years as an aid to maintaining or further reducing their weight. Subjects took an average of 12 Fibre Trim tablets per day and either maintained their reduced body weight or experienced a further weight reduction (RX 344, p. 2). Average weight loss at the five-year follow-up was an additional 2.4 kg (in addition to the 11.3 kg lost during the original study) (RX 197, pp. 7, 17-18, RX 344, p. 2).

#### 4. Post-Dissemination Clinical Trials

*a. SOLUM II: "The Influence of a High-Fibre Diet on Body Weight, Serum Lipids and Blood Pressure in Slightly Overweight Persons"*

169. This study was conducted by Toril Solum (principal investigator), Kjeld Rytting, E. Solum, and Stig Larsen in Scandinavia, and was published in the International Journal of Obesity in 1987. Its purpose was to investigate, among other things, whether Fibre Trim, when taken in conjunction with a calorie-restricted diet, could result in a higher weight loss compared to diet alone (RX 335, pp. 1-2). The study was randomized, placebo-controlled and double-blinded and included 71 subjects, each of whom was told to follow a 1200 calorie diet for a 12-week period (RX 335, p. 2, RX 338, pp. 3, 6-9; Tr. 2986, 3238).

170. Thirty-seven subjects were placed in the Fibre Trim group and received 20 Fibre Trim tablets per day; 34 subjects were placed in the placebo group and received 20 placebo tablets per day. Both groups were instructed to take five tablets with water four times a day 30 minutes before each meal (RX 335, p. 2, RX 338, pp. 3, 6-9; Tr. 2986, 3238-39).

*b. ROSSNER: "Weight Reduction with Dietary Fibre Supplements"*

171. This study was conducted by a team of researchers consisting of Stephan Rossner (principal investigator), Dan Von Zweigbergk, Agneta Ohlin, and Kjeld Rytting. The study was conducted at the Karolinska Hospital in Stockholm, Sweden, and was published in Acta Medica Scandinavia, the Scandinavian medical journal, in 1987. The aim of the study was to investigate whether a dietary fiber supplement program using Fibre Trim could improve the results of a conventional weight-reduction regimen (RX 329, p. 1, RX 334, p. 4).

172. Rossner was a randomized, placebo-controlled, double-blinded study involving 59 subjects which was conducted over a two-month period (RX 329, pp. 1-3, RX 334, pp. 3, 6). All the subjects were told to follow a 1400 calorie diet (RX 329, p. 2). In addition, 31 subjects were given 18 Fibre Trim tablets per day, while 28 placebo subjects received a corresponding number of placebo tablets. Both groups were instructed to take six tablets with water three times a day

30 minutes before each meal (RX 197, pp. 11, 17-21, RX 329, p. 2, RX 334, pp. 3-4).

c. *EHMANN & RESSIN: "About the Significance of Dietary Fibre in the Dietetic Treatment of Overweight Individuals"*

173. This study was conducted by Dieter Ehmann and Wolfgang Ressin in Germany and published in a German medical journal entitled *Pharmazeutische Zeitung* in 1985. Its purpose was to investigate the effect of Fibre Trim tablets as part of a weight reduction program for overweight individuals. The study was conducted over a four-week period and involved 40 subjects who came from a rehabilitation institution for organic and functional cardiovascular disorders (RX 339, pp. 1-2). This was a single-blinded study; that is, although the investigator knew which tablets (Fibre Trim or placebo) the subjects were receiving, the subjects did not know (RX 197, p. 19).

174. Subjects were divided into two groups of 20 subjects each based on the number of calories in their recommended diet; one group was told to follow an 800 calorie diet; the other group was told to follow a 1200 calorie diet (RX 339, p. 2, RX 342, pp. 3-4; Tr. 2668, 3016-17, 3259-60).

175. Each group was divided again into two subgroups -- one receiving Fibre Trim and one receiving placebo tablets; the Fibre Trim subjects were given up to five Fibre Trim tablets, three times a day before meals; the placebo group took a corresponding number of placebo tablets (RX 339, p. 2).

d. *BIRKETVEDT: "The Effect of a Combination of Fibre Tablets and Reduced Energy Intake in the Treatment of Overweight and on Maintenance of an Achieved Weight Reduction"*

176. This study was conducted by Grethe Birketvedt and Kjeld Rytting in Norway. The results are still in manuscript form (RX 348).

177. Birketvedt was a randomized, double-blinded, placebo-controlled study involving 53 subjects which lasted 26 weeks (RX 197, pp. 11, 17-21, RX 348, pp. 3, 6).

178. All subjects were told to follow a 1200 calorie diet. Twenty-five subjects received placebo tablets, while 28 received Fibre Trim tablets (RX 197, p. 11, RX 348, pp. 6-8). The subjects took 22

tablets per day, six before each meal and four at 3 p.m., until ideal body weight was attained, at which time the dosage was reduced to 15 tablets per day (RX 197, pp. 11, 17-21, RX 348, p. 6).

#### 5. Schering's Analysis of the Clinical Trials and Other Data Provided By Farma Food

179. In the latter half of 1984, Schering assembled the Second Generation Team, composed of company employees from various scientific disciplines, to review scientific data, including the Hessel, Solum I and Rytig studies provided by Farma Food (Tr. 2406-07, 2458, 2494, 2789-90; CX 333, pp. 169, 174). In late September or early October 1984, a member of that team, Dr. Iezzoni, was asked by his superior to review this package of material over a weekend (Tr. 2406, 2414). Included in this package was a memorandum which set out various potential performance claims for Fibre Trim (Tr. 2409; CX 15, p. 2; RX 211). Dr. Iezzoni reviewed the package of data to determine if the materials therein would support those performance claims (Tr. 2410) and prepared a memorandum that summarized his opinions and comments from that review (Tr. 2408; CX 15, pp. 5-7).

180. Dr. Iezzoni's memorandum was critical of the Rytig and Solum I studies:

I doubt that the clinical data would be adequate to support an NDA (New Drug Application] for prescription or for OTC marking as a weight loss/control product. The two controlled, blinded clinical studies are flawed, are not of adequate duration, and do not cover a reasonable spectrum of obese patients to evaluate benefit versus risk. There are few or no data to support some of the projected product performance claims (CX 15, p. 5).

Despite these reservations, Dr. Iezzoni's superior did not discuss the memorandum with him (Tr. 2490).

181. Subsequent to the preparation and distribution of Dr. Iezzoni's memorandum, a meeting of the Second Generation Team was scheduled to discuss the adequacy of the materials Dr. Iezzoni had reviewed as substantiation for the proposed Fibre Trim claims (CX 15, p. 1, CX 16). Dr. Iezzoni's memorandum summarizing his opinions and criticisms of the materials he had reviewed was attached to the agenda for that meeting (*see* CX 15), but he did not attend this meeting, and no one briefed him about it (Tr. 2493-94).

182. No member of the Second Generation Team had any expertise in weight loss (Tr. 2496-97; *see* Tr. 2351). Although Dr. Albu prepared a monograph on Fibre Trim to assist Schering employees in analyzing product claims (Tr. 2191-92) and discussed Fibre Trim with Dr. Vahouny, a Fibre Trim consultant and expert on dietary fiber (Tr. 2193-95), Schering never consulted with an independent expert in weight loss or fiber with regard to the adequacy of substantiation data prior to the dissemination of its Fibre Trim advertising (Tr. 2816).

183. All Fibre Trim advertisements and promotional materials were reviewed by Schering's medical, regulatory, legal marketing, and professional services departments (Tr. 1489-90, 2260, 2536). The stated purpose of this review process was to ensure that the claims being made were scientifically accurate and supportable (*see* Tr. 2260, 2536).

184. None of the materials that were believed to substantiate the claims in a proposed advertisement were circulated with that advertisement during the review process (Tr. 1520). The reviewers concluded that the proposed advertisement copy was supportable if, in their judgment, it was consistent with the approach already approved by the Second Generation Team (*see* Tr. 1521, 2538).

185. Farma Food had conducted or sponsored more scientific studies of the efficacy of Fibre Trim than it provided to Schering (CX 110, CX 158, CX 162, p. 2; *see* RX 200, p. 18; CX 208), some of which did not show that Fibre Trim was more efficacious than the placebo as a weight loss product (*e.g.*, CX 110, CX 159, CX 162, p. 2).

186. One weight loss study by Dr. Anderson of Denmark "did not show [a] significant difference between fiber tablets and placebo . . ." which, according to Farma, was due to some unspecified technical difficulties in the design and conduct of the study (CX 162, p. 2).

187. Dr. Albu, Dr. Iezzoni and Mr. Campbell of Schering's marketing department knew of this study (CX 162; *see* Tr. 310, 2325, 2492). Other Schering employees who were reviewing the scientific support for proposed Fibre Trim weight loss claims in late 1984 (*e.g.*, Dr. Giaquinto, Ms. McGee and Mr. Walsh) should have been aware of the existence of this Anderson study based upon the summary of it contained in Dr. Iezzoni's memorandum evaluating substantiation materials (*see* CX 15, p. 7, CX 16). No one from Schering ever asked Farma Food to provide a copy of Dr. Anderson's study (Tr.

381, 2325, 2492, 2874-75; *see* CX 333, p. 200) but Dr. Levine testified that, regardless of the purported “technical difficulties,” he would consider such a study highly relevant to a proper scientific evaluation of Fibre Trim’s potential efficacy (Tr. 800-01).

188. At the time Dr. Iezzoni reviewed the scientific data provided by Farma Food as support for Fibre Trim’s weight loss claims in late 1984, Dr. Kissileff’s 1983 food intake study comparing Fibre Trim to a placebo which he undertook for Farma Food (Tr. 681; CX 110) was completed and, according to him, failed to show that Fibre Trim had any effect on food intake (Tr. 689-90).

189. Prior to January 1986, when Schering began to advertise Fibre Trim on a national basis (Tr. 1502; CX 310), an eight week weight loss study by Dr. Brock of the Medical University of South Carolina comparing Fibre Trim to a placebo was completed (Tr. 376). This study, which was sponsored by Farma Foods, failed to show that Fibre Trim was significantly more efficacious than the placebo in achieving weight loss (CPF 269-272).

190. The Kissileff and Brock studies were in the possession of Mr. Bonfield, Farma Food’s U.S. representative (Tr. 347, 359-60, 370; CX 208, p. 5), and its liaison with Schering with regard to the marketing of Fibre Trim (Tr. 307-08). No one from Schering ever sought to obtain from Mr. Bonfield any studies that failed to demonstrate Fibre Trim’s efficacy as a weight loss product (Tr. 381, 2492; *see* Tr. 2325).

191. In April 1984, Farma Food’s U.S. subsidiary cosponsored a fiber symposium in the United States at which scientists reported findings from their research (Tr. 430). One of those scientists, Dr. Rossner, reported the results of his weight loss research comparing Fibre Trim tablets to placebo tablets (*see* Tr. 446-47; CX 63). He reported that the Fibre Trim group experienced a mean weight loss of 7.0 kg and the placebo group experienced a mean weight loss of 6.0 kg (Tr. 447; CX 63, p. 5). This difference of 1.0 kg was reported as not statistically significant (Tr. 446-47; CX 63, p. 5, CX 234, pp. 2-4). Subsequent analysis of the results of this study correcting data entry errors resulted in the conclusion by Dr. Larsen that its results were statistically significant (Tr. 3010-14).

192. No one from Schering ever asked Mr. Bonfield if there was any scientific testing that failed to demonstrate Fibre Trim’s efficacy as a weight loss product (Tr. 381, 2492), or ever reviewed any

scientific testing of Fibre Trim that failed to demonstrate its efficacy as a weight loss product (Tr. 2832; CX 333, p. 29).

193. Both Dr. Levine and Dr. Levitsky testified that a reasonable scientist reviewing the Rossner study in addition to Solum I, Rytting and Hessel, would conclude that these materials did not provide a scientific basis for the proposition that Fibre Trim was an effective weight loss product (Tr. 804, 997).

194. Schering also possessed a Farma Food document indicating that 24 studies had been conducted on overweight subjects (RX 200; Tr. 2281-82), but there is no evidence that any employee asked for the results of these studies.

195. On May 1, 1987, Schering's senior brand manager for the Fibre Trim product sent a memorandum to various people having responsibility for Fibre Trim advertising claims and their substantiation. The memorandum enclosed a copy of the Solum II study which had just arrived from Farma Food, and asked for the recipients' evaluation of it as "a proof source for the claims we currently make. . . ." The memorandum also thanked the recipients for their "support of marketing in the face of adversity and ambiguity ('murky' clinicals, questionable ingredients lists, etc. . . .)." The memorandum concluded with the request that the memorandum be destroyed after receipt "so no outsider sees the last line [regarding murky clinicals] . . . ." (CX 170, p. 1).

196. Finally, an advisory expert panel to the FDA evaluated the safety and efficacy for weight control of several types of fiber and concluded, in a 1982 Advance Notice of Proposed Rulemaking, that "the value of bulk producers in reducing weight by controlling appetite has not been established" (CX 81, p. 14). As evidenced by the FDA's 1990 Proposed Rule on Weight Control Drug Products for the Over-The-Counter Human Use, this 1982 conclusion has not been superseded (CX 471, pp. 2-4). Fibre Trim is in the same category as these other fiber-based hydrophilic bulk-producing weight control products evaluated by the FDA panel (CX 22; Tr. 2326-28; *see* Tr. 359).

197. Dr. Albu was aware of the existence of this FDA review at the time Schering was developing its Fibre Trim campaign, but did not know whether or not the fiber products evaluated by the panel had been found effective (Tr. 2328). Dr. Giaquinto was also aware of the FDA's review of the efficacy of various fibers as weight loss agents but did not consider it in evaluating claims for Fibre Trim (CX 333, pp. 21, 109).

## 6. The Relationship Between Schering's Advertising Claims and the Studies Relied On

### *a. The Weight Loss Claim*

198. Schering relies on studies which were conducted before (“pre-dissemination”) and after it began advertising Fibre Trim as support for its claims. However, these studies used Fibre Trim in conjunction with a restricted calorie diet ranging from 800 to 1400 calories per day (CX 66, CX 67, CX 68, CX 166, CX 255, CX 256), and none of the experts testifying for either party said that it would be scientifically sound to infer from their results that consumers using Fibre Trim without deliberately following a reduced calorie diet would lose weight. Proof of this claim would require studies in which Fibre Trim was tested in subjects not on a diet. Schering has not offered such studies (Tr. 826, 1031, 2472-76, 2542-43, 2771, 3101-02, 3295, 3707; CX 333, pp. 17, 27, 69, 87).

199. Dr. Giaquinto, Schering's vice president of Regulatory Affairs at the time the challenged advertisements were first disseminated, testified that the studies would not support a claim that Fibre Trim would be an effective weight loss product without an accompanying reduced calorie diet and an exercise program (CX 333, pp. 27, 69, 87, 101, 193; *see also* Tr. 2541-43).

### *b. The Weight Maintenance Claim*

200. The Rytting, Solum I and Hessel studies do not support the weight maintenance claim, for the first two were of too short a duration (eleven and eight weeks) (Tr. 792, 799, 979, 3699), and the Hessel study, while of adequate duration, was not placebo-controlled, blinded, or randomized (Tr. 949, 2216). In fact, Dr. Iezzoni, Schering's Director of Medical Services, disregarded that study while he was evaluating the support for Fibre Trim's performance claims (Tr. 2460). Therefore, at the time the weight maintenance claim was made, Schering had no competent and reliable scientific basis for that claim, and no valid post-dissemination studies support it.

*c. The Appetite Suppressant Claim*

201. None of Schering's pre-dissemination studies report on caloric intake, the only meaningful and objective measure of a product's appetite suppressant properties, and they do not therefore support the appetite suppressant claim (CX 153, CX 166, CX 255, *see* CX 333, p. 79; Tr. 679-80, 781, 789, 793, 799, 949-50, 958, 979-81, 997-98).

202. Schering's advertising expressly refers to Fibre Trim's ability to reduce hunger pangs or to make one feel full, but Dr. Albu testified that neither the Solum I nor Rytig studies provide any information about its effect on hunger, fullness or appetite reduction (Tr. 2313, 2319) and that these studies did not support claims of this kind (Tr. 2265).

203. While Dr. Iezzoni testified that the Rytig study supported a hunger reduction claim (Tr. 2481), the report of that study does not refer to this subject (*see* CX 368), and Dr. Iezzoni could not identify at trial the version of the study he relied on (Tr. 2483-84). Therefore, at the time the appetite suppressant claims were made, Schering had no competent and reliable scientific basis for that claim, and no valid post-dissemination studies support it.

7. Analysis of the Weight Loss Studies

*a. In General*

204. The studies relied upon by Schering do not support its weight loss claims because they involved dieting subjects. In addition, although it is disputed, expert testimony elicited by complaint counsel leads to the conclusion that the studies are flawed, even with respect to support for claims which might be based on them (*i.e.*, that Fibre Trim is effective when taken in conjunction with a reduced calorie diet).

205. Although analysis of the individual merits or faults of the studies is of paramount importance, their results must be viewed in light of the fact that, at the time Schering disseminated its Fibre Trim advertising, other evidence suggested that fiber's ability to cause weight loss was questionable (Tr. 994, 3806).

206. The Brock and Kissileff studies certainly put into question the efficacy of Fibre Trim for weight loss and appetite suppression,

and an October 1985 report on fiber developed by an expert advisory committee for the Canadian Health and Welfare Bureau which reviewed the state of scientific knowledge, concluded that “[t]he evidence to date is in no way sufficient either to establish weight reduction as a physiological effect of fibres, or to determine the role of fibres in weight loss preparations” (CX 78, p. 24). Dr. Anderson, one of Schering’s experts, agreed that as of the date of this report, scientific documentation was lacking for prescribing dietary fiber for weight loss (Tr. 3806), and other experts testified that the role of fiber in weight loss, if any, has still not been established (*see* Tr. 781, 1146-47, 3795; CX 78, p. 24, CX 90, pp. 74-79, CX 480). Very recently - in 1990 - a report on fiber prepared by the British Nutrition Foundation’s Task Force found: “many experiments have been done in which fibre supplements of all kinds have been taken with meals . . . and weight loss is rarely, if ever, reported” (CX 207, p. 81).

207. Furthermore, those studies that have reported a weight loss effect from a quantity of fiber similar to that provided by Fibre Trim have involved soluble fiber such as guar and glucomannon which have different properties than the fiber in Fibre Trim (Tr. 768-69; *see* 482-87) and the results of these studies, according to Drs. Levine and Levitsky, may not be extrapolated to Fibre Trim (Tr. 769, 988-94).

*b. The Pre-Dissemination Studies*

(1) Hessel

208. Schering did not rely on the Hessel study as substantiation for its claims and since it was not blinded, randomized or placebo-controlled, it could not have served that purpose (Tr. 2460, 2587; RX 197, pp. 6-9).

(2) Rytting

209. Drs. Levitsky and Levine testified that this study was so flawed that it could not serve as the basis for any claims as to Fibre Trim’s efficacy.

210. Schering’s promotional literature states that the daily dosage of Fibre Trim is 15 tablets (CX 280, p. 2, CX 288, p. 10, CX 310, p. 2), but subjects in the Rytting study were given nearly twice that amount (CX 255), and it is not scientifically sound to conclude that

because daily consumption of 28 Fibre Trim tablets produces a particular result, 15 will also do so (Tr. 718, 794-95, 975-76; *see* Tr. 3104). Thus, even if the Rytzig study were valid in all respects, it could not substantiate a claim for the recommended dosage of Fibre Trim (Tr. 794, 974-80, 2528-29, 3103-04, 3695, 3807).

211. Other flaws in this study were identified: The placebo tablets contained 54 more calories than the fiber tablets (RX 324, p. 2; Tr. 793-94, 960) and if the weight loss difference between the groups is adjusted to take this into account, the results are not statistically significant using a two tailed test (Tr. 1069-75).

212. There were a total of nine withdrawals during the Rytzig study, eight placebo and one fiber (CX 255, p. 3 (& Table 3); Tr. 796-98, 962-64). Because there were considerably more withdrawals in the placebo group, and withdrawals were assigned their highest recorded weight (CX 255, p. 2), the actual weight loss of that group was diluted in comparison with the Fibre Trim group, biasing the results in favor of the latter (Tr. 796-98, 963-64, 967; *see* Tr. 3078).

213. Dr. Hurley, who testified for Schering and analyzed the weight loss studies, used subject discontinuance rates as a measure of how well-controlled those studies were (RX 197, pp. 7-8; Tr. 2620). He stated that even if intention-to-treat analysis were used, he would have "grave concerns about the interpretability of the result[s]" of a study in which more than 20 percent of the subjects discontinued (Tr. 2707). In the Rytzig study a total of 11 placebo subjects, or 24 percent of the 45 originally enrolled, discontinued (CX 255, p. 3). Finally, Dr. Iezzoni testified that he was unsure whether the sample used in this study could be generalized to the U.S. population (Tr. 2472-74).

### (3) Solum I

214. A major criticism of this study is that the description of its design, implementation and results is so brief that one cannot assume its validity and reliability (Tr. 790-91, 955-56; *see* Tr. 320-21, 2726-27, 3696-97). Although he testified in support of Schering's studies, Dr. Feinstein stated: "If the Solum I study were submitted to my journal, we would not accept it because it doesn't have enough detail" (Tr. 3577).

215. Specifically, the report does not reveal the mean beginning or ending weights of the two groups, the amount of weight loss, the

caloric content of the placebo tablets, and it contains no tables presenting any data (Tr. 791, 954, 956). Because of the report's brevity, Dr. Giaquinto testified that:

This study was not meant or at least was not used by me to stand alone and was not looked to have the type of criteria we were looking to get a drug which this is not -- we never classified as such -- approved or qualified for an adequate and well-controlled trial

(CX 333, p. 77). Dr. Levine concluded that the description of the study is so sparse that: "We are supposed to believe that what they were presenting is true, but we're not given the evidence for that" (Tr. 791).

216. Because of the lack of detail in this study, Dr. Iezzoni "assume[d] that [the investigator] did the appropriate things that were necessary for an evaluation of this material" (Tr. 2500) and Dr. Hurley concluded that it did not satisfy randomization criteria (RX 197, p. 20; Tr. 2726). Although Solum I did not reveal whether data from subjects who discontinued was included in its analysis, he assumed that the intention-to-treat principle was followed (Tr. 2727-28).

217. Dr. Larsen's 1983 evaluation of Solum I expressed concern about its lack of data:

the study has certain shortcomings both in the form of lacking data and dropout routine and lack of initial body weight observations. So this result will need to be verified by new studies of a design eliminating the abovementioned shortcomings

(RX 320, pp. 4-5).

### *c. The Post-Dissemination Studies*

#### (1) Ehmann & Ressin

218. At the end of the four-week period of this study, the fiber group averaged a slightly greater weight loss than the placebo group, but the report of the study does not claim that the difference is statistically significant (CX 67).

219. In addition, Dr. Feinstein concluded that while Ehmann & Ressin is "supportive" because it showed results consistent with the

other studies, it “is not an acceptable study because it wasn't randomized and it wasn't double blind” (Tr. 3587-88).

### (2) Solum II

220. According to the published report of this test, at the end of 12 weeks, the fiber group had lost more weight than the placebo group. This difference was statistically significant (CX 66).

221. Despite the statistically significant weight loss in the fiber group, Drs. Levitsky and Levine concluded that Solum II did not support Schering's claims because it is not scientifically appropriate to extrapolate from the effects of this study which used 20 Fibre Trim tablets to the probable effects of using the recommended dosage of 15 tablets. In addition, because these subjects were consuming a baseline diet containing 25 grams of fiber per day, the study's results cannot be generalized to the American population, whose fiber intake is smaller (Tr. 792, 821, 1012-13).

222. Other problems with this study were pointed out: The published study does not reveal the number of subjects or the amount of weight lost (Tr. 818-19). While the abstract refers to 60 participants, the text mentions 70 (CX 66, pp. 2, 4) and the statistical report indicates that 71 were enrolled (RX 337, p. 11, RX 338, p. 3). The abstract and text do not agree as to the weight lost by the placebo group (compare CX 66, p. 2 with CX 66, p. 4).

223. Dr. Levitsky reanalyzed the data in Solum II taking into account the fact that the placebo tablets provided 60 more calories per day than the fiber tablets (Tr. 820, 1011, 1083-86; CX 66, p. 3, CX 332) and found that, using a two tailed analysis, the difference in weight loss between the fiber and placebo groups was not statistically significant (Tr. 1088). Furthermore, Dr. Larsen, a co-author of this study, arrived at statistical significance for this study only after data manipulations which may not have been appropriate (Tr. 3130-34; RX 338, p. 3).

### (3) Rossner

224. At the end of this two-month study, the fiber group averaged a one kilogram greater weight loss than the placebo group (CX 256), and the 1987 report of this study concluded that this difference was statistically significant.

225. Dr. Levine testified, however, that several discrepancies raise serious questions about the credibility of this study (Tr. 816-17), particularly an earlier report of what was apparently the same study which states that the weight loss was not statistically significant (*see* Tr. 3014; CX 63, p. 5; RX 333, p. 11).

226. The published report states that the data of discontinuers was to be included in the analysis of results (CX 256, p. 2), but the discussion of the results excludes the six subjects who did not complete the study (Tr. 1004-05). As in other studies, the placebo tablets provided more calories than the Fibre Trim tablets (Tr. 811-12, 1003).

227. As with the Solum I, Rytting, and Solum II studies, Dr. Levitsky performed a reanalysis of the Rossner data, excluding the subjects who did not complete the study (Tr. 107883; CX 331) because inclusion of data for these subjects biased the study in his opinion (RX 329, p. 3; Tr. 1081-82). While the published report does not specify which group these subjects had been assigned to, the backup data reveals that all were from the placebo group (CX 270, pp. 8-12). Including them in the data analysis as if they had participated in the study and lost no weight penalized the placebo group.

228. If Dr. Levitsky's analysis of the Rossner study is accepted, it demonstrates that, although the loss was not statistically significant, the placebo subjects who completed the study actually averaged a slightly greater weight loss than did the fiber subjects (Tr. 1082; CX 331, p. 2). Dr. Larsen, who reanalyzed this and other studies for Schering, agreed that, if it is proper to exclude early discontinuers from the data analysis, the fiber tablets did not cause greater weight loss than did the placebo tablets (Tr. 3121-22). This is true even without adjustment for the caloric differential between the fiber and placebo tablets. If the caloric differential were accounted for, the placebo group's weight loss would be even further enhanced (Tr. 1080).

#### (4) Birketvedt

229. In this 26-week study, the subjects were given, along with a reduced calorie diet, 22 Fibre Trim or placebo tablets daily until reaching ideal weight, and then a maintenance dose of 15 tablets (CX 68, p. 6). Drs. Levitsky and Levine concluded that since the test dosage was greater than Fibre Trim's recommended dosage,

Birketvedt's results could not substantiate the Fibre Trim claims (Tr. 823-24, 1020-23).

230. Both the Fibre Trim and placebo groups lost statistically significant amounts of weight during the 26 weeks of the study (Tr. 3197; RX 348, p. 8), and the mean weight loss was greater in the Fibre Trim group than in the placebo group from weeks 4 through 24 by a statistically significant amount (Tr. 3553; RX 348, pp. 8-11).

231. However, during the final two weeks of this study, the Fibre Trim group gained weight while taking 15 tablets per day; this gain neutralized the weight lost earlier in the study, so that, at its end, there was no longer a statistically significant difference between the fiber and placebo groups (Tr. 823-24, 1020, 1023, 3169).

232. Dr. Feinstein testified that to demonstrate the efficacy of a product for weight maintenance, a study should be continued for longer than 6 months, and he agreed that the results of the Birketvedt study could not be considered as proof of what its results would have been if it had been continued for more than 26 weeks (Tr. 3698-99).

233. Drs. Levitsky and Levine concluded that the seven studies relied on by Schering do not, either individually or collectively, constitute reliable support for Schering's weight loss, weight maintenance or appetite suppression claims. Even if Schering's post-claim evidence is considered (*infra*), they concluded that each of the studies is critically flawed, contains numerous inconsistencies, and do not in the aggregate support Schering's claims, for it is scientifically improper to conclude that several flawed studies can be considered, if viewed together, as reliable scientific evidence (Tr. 825-27, 980-81, 1030-39).

## 8. Schering's Defense of the Weight Loss Studies

234. Schering answers the criticisms of complaint counsel's experts by pointing out that the studies it relied upon met some of the recognized standards for clinical trials:

a. Solum I, Rytting, Solum II, Rossner, and Birketvedt were randomized (RX 194, p. 4, RX 195, p. 1, RX 197, p. 19, RX 317, p. 2, RX 321, pp. 3-4, RX 324, p. 2, RX 327, pp. 4, 8, RX 329, p. 1, RX 335, p. 1, RX 338, p. 3, RX 348, p. 6).

b. Solum I, Rytting, Solum II, Rossner, and Birketvedt were double-blinded (RX 194, p. 4, RX 195, p. 1, RX 197, p. 19, RX 317,

p. 2, RX 321, p. 4, RX 324, p. 2, RX 327, p. 4, RX 329, p. 1, RX 335, p. 1, RX 338, p. 3, RX 348, p. 3). Ehmann & Ressin was a single-blind study (RX RX 197, p. 19).

c. Solum I, Rytting, Solum II, Rossner, Ehmann & Ressin, and Birketvedt were placebo-controlled studies (RX 317, p. 2, RX 321, pp. 3-4, RX 324, p. 2, RX 327, p. 3, RX 329, p. 1, RX 334, p. 3, RX 335, p. 1, RX 338, p. 3, RX 339, p. 2, RX 348, pp. 3, 6).

d. Solum I, Rytting, Solum II, Rossner, and Birketvedt were analyzed following the intention-to-treat principle (RX 320, p. 3, RX 321, pp. 3, 6, RX 324, p. 2, RX 327, pp. 3-4, 7, RX 334, p. 5, RX 335, p. 2, RX 348, p. 7; Tr. 2924, 2950).

e. With the exception of Birketvedt and Hessel, the results of each Fibre Trim clinical study demonstrate that the Fibre Trim group lost a statistically significant greater amount of weight than the placebo group (RX 317, p. 2, RX 320, pp. 3-4, RX 321, pp. 3, 8, 12, 15-16, RX 324, pp. 2-3, RX 327, p. 13, RX 329, p. 3, RX 334, p. 7, RX 335, p. 3, RX 338, p. 19, RX 342, p. 15, RX 403; Tr. 3243-45). The results of Solum II, Ehmann & Ressin, and Rytting are also significant when a two-tailed test is used (RX 33, p. 19, RX 327, p. 13, RX 342, pp. 5, 15; Tr. 2953-54, 2995, 3020).

f. Medstat, the research institute that analyzed the Fibre Trim clinical studies, reanalyzed Solum I, Rytting, Rossner, and Solum II, adjusting for the additional calories contained in each placebo tablet (RX 321, p. 10, RX 327, p. 15, RX 334, p. 8, RX 338, p. 8; Tr. 2949, 2956-60, 2980-81, 2994-95, 3012, 3235, 3249, 3255).

g. After adjusting for the additional placebo calories, Medstat concluded that the Fibre Trim group lost a statistically significant greater amount of weight than the placebo group in the Solum I, Rytting, Rossner and Solum II studies (RX 321, p. 15, RX 327, pp. 16-17, RX 334, p. 9, RX 338, p. 19; CX 329, p. 5, CX 330, CX 332, pp. 5-6, CX 393; Tr. 1113-14, 1143-44, 1151, 2949, 2956-62, 2980-81, 2994-95, 3012, 3235, 3249, 3255).

235. Since each of the studies relied on by Schering involved subjects who were consciously following a diet program, it is irrelevant whether those studies were adequate and well-controlled, for Schering's advertisements did not make it clear that Fibre Trim might be an effective weight loss and weight maintenance product only if consumers -- along with taking Fibre Trim -- also consciously followed a reduced calorie diet program.

236. Furthermore, statistical significance alone does not validate a study, for the question remains: was the observed difference clinically significant or “clinically trivial” (CX 492, pp. 546-47). With respect to weight loss studies, some experts believe that a weight loss product should produce a difference of at least one-half pound per week between placebo and treatment groups (Tr. 813). Such a weight loss would not only be statistically significant but clinically significant.

237. The FDA’s proposed monograph for clinical trials of OTC weight control drug products offers some guidance in this regard. While it does not mandate the amount of weight loss that an effective weight loss product must produce, it assumes that subjects receiving the placebo will lose one pound per week, while those receiving an effective weight loss treatment will lose 1.5 pounds per week (CX 81, p. 17).

238. The published results of the Fibre Trim studies reveal that they do not meet this standard (*see* Tr. 813, 824).

239. If the results of a study cannot be applied to the actual conditions under which the tested product will be used they are meaningless. The Rytting study fails this test and its statistical significance does not, therefore, prove the value of the recommended dosage of Fibre Trim.

240. The Hessel study was not randomized or placebo controlled and the results of the Rytting study cannot be extrapolated to actual Fibre Trim dosage; therefore, Schering did not possess two adequate, well-controlled clinical studies supporting the claim that Fibre Trim is an effective weight loss or weight maintenance product when taken in conjunction with a reduced calorie diet.

241. Since Schering had no pre-dissemination basis for the claim which it says it made, it is not essential to decide whether it possessed two adequate, well-controlled post-dissemination clinical trials, but some comment on the adequacy of those trials would not be out of place.

242. The post-dissemination studies are problematic, particularly Rossner, which exemplifies the problem of relying on subjects who discontinued treatment. Respondent’s experts (Drs. Ahern, Hurley and Larsen) testified that inclusion of data for all subjects randomized into a study regardless of whether they complete the study (the “intention-to-treat” principle) is the only acceptable way to treat the results of a study (Tr. 2613, 2622, 3051, 3317-20).

243. If Rossner is analyzed according to this principle, the results are statistically significant; however, if early discontinuers from the study are excluded, the results are not significant (Tr. 3121-22).

244. Dr. Feinstein, who claimed that Rossner provided only marginal support for Schering's claims (Tr. 3677), acknowledged that there are differing views among experts regarding the propriety of applying the intention-to-treat principle and stated that the evaluation of that study as support for the product's efficacy depends on "which church I'm in. In one church the study will get full credit. In the other church it won't" (Tr. 3678; *see* Tr. 798).

245. In fact, some of Schering's own experts do not adhere to the intention-to-treat principle. Dr. Eastwood does not use the intention-to-treat principle in his clinical studies (Tr. 3487), and Dr. Anderson usually requires that subjects consume 75 to 80 percent of the product before including their data in a study analysis, an approach which he prefers over the intention-to-treat principle (Tr. 3785-86) (*see also* CX 515, p. 8; RX 284, p. 4, RX 291, pp. 23-26).

246. Dr. Giaquinto testified in a deposition that he did not believe that the intention-to-treat principle was necessarily the best approach in the context of a weight loss drug study (CX 333, p. 15), and that in research conducted by Schering, the data of discontinuers is included in safety analyses of drugs, but not in efficacy analyses (CX 333, pp. 15, 83, 86).

247. In a study conducted by Dr. Michael Follick of Brown University investigating the efficacy for weight loss of Fibre Trim FruitTabs, he excluded 32 of the 103 subjects originally enrolled in the study "because they either did not complete the project or had a substantial amount of missing data in their measures" (CX 475, p. 6). The results were analyzed based only on the data of those who completed the study (CX 475, pp. 6, 12-13; Tr. 3368-69).

248. There are also problems with Ehmann & Ressin, Solum II and Birketvedt which convince me that, whether one looks at pre- or post-dissemination studies, Schering's weight loss and weight maintenance claims were not substantiated and that Schering should have questioned the results of those studies when they were analyzed, particularly in view of the skepticism in the weight-loss community about the efficacy of fiber for weight loss and scientific studies conducted or sponsored by Farma Food which did not substantiate a weight loss claim (CX 110, CX 159, CX 162, p.2) and whose

existence was known of by Schering employees or of which they should have been aware.

249. Despite the obvious deficiencies of the pre-dissemination studies, and the existence of contrary evidence about Fibre Trim's efficacy, no one at Schering who was responsible for determining whether its weight loss claims were substantiated asked to inspect their protocols, patient data forms or statistical analyses (Tr. 2497, 2509, 2540-41; *see* CX 333, p. 9).

250. Finally, analysis of their validity cannot ignore the apparent lack of peer review for these studies and the participation of the same investigator in several of them. The list of authors of the seven studies relied on by Schering is varied, but one individual, Kjeld Rytting, played a significant role in the design and preparation of several of them: he was the primary author of the Rytting study (CX 255), the co-author as well as the monitor for the Solum II study (CX 66; Tr. 3127), and a co-author of the Rossner and Birketvedt studies (CX 68, CX 256). While not listed as a co-author of Solum I, he was responsible for drafting the article to be submitted for publication (Tr. 3152; CX 366, p. 3). Mr. Rytting was, throughout the relevant time period, Medical Director for Farma Food, the product's manufacturer (Tr. 3056).

251. The Hessel and Birketvedt studies (CX 53, CX 68) are unpublished manuscripts. The record is silent as to whether the European journals in which Rytting, Solum I, Ehmann, and Rossner appeared require peer review; and while Solum II was published in the International Journal of Obesity, a peer review journal of which Dr. Levitsky is a regional editor, the study appeared in a supplement of the journal that consisted entirely of papers presented at a symposium on weight loss. Such supplements are not subjected to the journal's ordinary peer review process (Tr. 1010).

### *G. Substantiation For The Health Benefits Claim*

#### 1. The Benefits of a High Fiber Diet

252. Experts called by both parties agreed that increased intake of dietary fiber may be associated with a variety of health benefits including prevention and treatment of colon cancer, coronary heart disease, obesity, diabetes, irritable bowel syndrome, diverticular

disease, and constipation (Tr. 495, 533, 1282-83, 3457, 3469, 3754, 3845, 3906; CX 90, pp. vii-viii, CX 92a, p. 15; RX 83, p. 1492).

253. Because of this association, several health research organizations, including the National Cancer Institute, the Department of Health and Human Services, the Department of Agriculture, the National Institutes of Health, the National Research Council of the National Academy of Sciences, and the Federation of American Societies for Experimental Biology (“FASEB”), have recommended in recent years that Americans increase their consumption of fiber-containing foods such as fruits, vegetables and whole grains. The recommendation is based on the observation that populations with diets high in those foods tend to have a lower incidence of heart disease, diabetes, cancers, and obesity (Tr. 495, 533, 1223, 1228, 1253-59, 1282-83; CX 90, pp. vii-viii, CX 92a, p. 15, CX 99a, pp. 12-13, CX 154, pp. 120-21). At issue is whether fiber supplements such as Fibre Trim provide the same health benefits as does a fiber-rich diet.

254. Several health organizations have stressed that the recommended increase in fiber consumption should be achieved by eating more high fiber foods, and not by taking fiber supplements (Tr. 533, 535, 1220, 1262-63; CX 78, p. 6, CX 90, p. 161, CX 92a, p. 15, CX 98, p. 6, CX 155, p. 8, CX 156, p. 4, CX 370, p. 6, CX 394, p. 15, CX 395, p. 5).

255. The National Academy of Sciences’ Diet and Health Report specifically states: “there is no conclusive evidence that the dietary fiber itself, rather than other nutritive and nonnutritive components of these foods, exerts a protective effect against these cancers. The committee does not recommend the use of fiber supplements” (CX 92a, p. 15). The National Cancer Institute has stated: “Since the evidence for a protective effect of fiber is generally from an association of dietary patterns in which fiber occurs as a complex mixture with other foods, the extrapolation to the possible beneficial effects from fiber supplements cannot be made at this time” (Tr. 1260; CX 370, p. 7; *see* CX 98a, p. 19). The Institute has further cautioned that “[f]iber supplements, unless they are ordered by your physician, aren’t the answer because all studies to date show that the protective effects are associated with fiber-rich foods” (CX 155, p. 8, CX 156, p. 4; *see* CX 78, p. 32, CX 97, p. 18, CX 395, p. 5).

256. Dr. Anderson testified that with respect to certain diseases such as coronary heart disease, scientific evidence does not support the proposition that fiber supplements provide all of the health

benefits associated with a high fiber diet from foods (Tr. 3758). In addition, because foods contain many different types of fiber, the health community recommends that consumers increase their fiber intake by eating a variety of fiber-containing foods (Tr. 495-96, 1262-63, 3471; CX 97, p. 17-18, CX 98a, p. 18-19, CX 100, p. 889, CX 155, p. 8, CX 395, pp. 2-3, 7, CX 495, p. 5).

## 2. Fiber and Colon Cancer

257. While populations consuming fiber-rich diets experience a reduced incidence of colon cancer, the specific role of fiber has not been discovered. Other constituents of fiber-containing foods, or the low fat content of high fiber diets, may be responsible for the protective association (*see* CX 92a, p. 15, CX 154, p. 121, CX 370, p. 7). There is, therefore, no basis for a contention that simply because Fibre Trim contains fiber it can provide the colon cancer reduction of a fiber-rich diet (Tr. 543-44, 1261-63).

## 3. The Laxative Benefits of Fibre Trim

### *a. Introduction*

258. Prior to dissemination of the challenged advertisements, Schering possessed several studies addressing Fibre Trim's laxative properties, although none of its employees testified that they or other Schering employees reviewed these studies (Tr. 2357, 2426, 2488, 2830-31; CX 333, pp. 18, 27-29, 283-84). Thus, the studies relied on by Schering at trial do not constitute pre-dissemination support for the claims made in its Fibre Trim advertisements. These studies are:

### *b. Schrivjer*

259. This study used 55 patients with irritable bowel syndrome (IBS) and other digestive complaints (Tr. 3418). Dr. Slavin, one of Schering's expert witnesses, testified that this study's parallel group design comparing Fibre Trim to wheat bran was appropriate (Tr. 3866) and she concluded that it showed that Fibre Trim is at least as effective as wheat bran (which is a potent fecal bulking fiber) (Tr. 3451; RX 179, p. 10) in increasing fecal weight, decreasing transit time through the gastrointestinal tract (GI) and increasing stool fre-

quency (Tr. 3866-67). Dr. Eastwood concluded that the increase in stool weight shown by the Schrivjer study is especially meaningful since subjects with IBS are less likely to show such an increase (Tr. 3421; *see also* Tr. 3866-67).

*c. Lambert's Clinical Trial No. 2*

260. This study used 42 patients with simple constipation (RX 187, p. 4299; Tr. 3872) and used a double-blind, parallel group design. Patients were randomly assigned to two groups, one consuming 10 grams of wheat bran and the other taking 12 Fibre Trim tablets per day (RX 187, p. 4299; Tr. 3426-27).

261. Drs. Slavin and Eastwood testified that this study showed that Fibre Trim increased stool frequency as effectively as wheat bran (RX 187, p. 4306; Tr. 3427, 3873), and that there was a significant decrease in GI transit time in the Fibre Trim group (RX 187, p. 4308; Tr. 3428, 3873). Dr. Story concluded that this study "suggests" that Fibre Trim is an effective laxative (Tr. 636-37).

*d. Lambert's Clinical Trial No. 3*

262. This study was conducted with 15 hospitalized, elderly patients suffering from constipation. The patients served as their own control. There was no parallel group taking a placebo or other product; rather, patient results were compared before and after taking Fibre Trim (CX 126, p. 2; Tr. 3432, 3874-75).

263. Drs. Eastwood and Slavin concluded that this study indicates that in a difficult group, elderly patients with constipation, Fibre Trim is effective in increasing stool weight and transit time (Tr. 3434, 3876). Asked to assume that Fibre Trim increased stool weight over 20 percent as indicated by this study, Dr. Lanza stated that it would be considered an effective laxative (*see* Tr. 1410).

*e. The Pulpeiro Study*

264. This randomized, double-blinded study was conducted with 40 patients with simple constipation, IBS, or uncomplicated diverticular disease (CX 122, pp. 2-3; Tr. 3435-38, 3877-78). In a crossover trial, subjects consume one product for a certain period; after a "washout" period when they consume no product, they are given a

second product for a period of time. Another group begins with consumption of the second product, then takes the first (Tr. 3437-38).

265. Drs. Eastwood and Slavin testified that Pulpeiro shows that Fibre Trim results in an increase in stool weight and a decrease in transit time compared to placebo (Tr. 3438-40, 3879). Again, assuming a 20 percent increase in stool weight, Dr. Slavin testified that Fibre Trim would be considered an effective laxative (*see* Tr. 1410).

*f. The Bjorneklett Study*

266. This crossover study, conducted with 20 patients complaining of chronic constipation, assigned them to either a wheat bran or Fibre Trim group for two months (RX 374, pp. 6-7; Tr. 3809). Both products were essentially equal in their laxative effect (RX 374, pp. 11, 13).

*g. The Vahouny Study*

267. According to Dr. Eastwood, this study using rats given various kinds of fiber (RX 184, p. 2) reveals that wheat bran and barley were effective in increasing stool weight; thus, barley, the principal component of Fibre Trim, and wheat bran are comparable in terms of fecal bulking ability (RX 184, p. 4; Tr. 3447).

*h. Analysis of the Laxative Studies*

268. There is a consensus in the scientific community that dietary fiber is useful in treating and preventing constipation (Tr. 3858; RX 179, p. 6, RX 188, p. 3 (“Undoubtedly, fibre supplements increase stool output and decrease transit time in healthy people”)).

269. If a fiber or fiber product produces a 20 percent increase in stool weight, it is considered to be an effective laxative (Tr. 1410). Wheat bran, which was used as a comparison for Fibre Trim in some of the studies (CX 123, CX 127, CX 128) is often used as a standard to determine whether other fibers are effective as laxatives (Tr. 565, 1410).

270. Dr. Slavin testified that, on the whole, the laxative studies provide reliable scientific evidence that Fibre Trim works as well as wheat bran and is effective as a laxative (Tr. 3881-82).

271. Drs. Story and Lanza concluded otherwise, pointing out that only the Pulpeiro study was placebo controlled (CX 122); furthermore, the studies did not indicate the type of wheat bran used, and there could therefore be no reliable conclusion about Fibre Trim's effects as compared with wheat bran (Tr. 586-87, 595, 599, 1322, 1344). Complaint counsel's experts identified other problems with the studies which make it impossible to conclude that Fibre Trim's laxative effects have been scientifically established (CPF 555-61).

272. It is probable that fiber supplements provide some of the health benefits that are provided by the fiber in foods (Tr. 630, 3748-50, 3857-58); and this is particularly true with respect to laxative effect (Tr. 3393, 3397, 3403, 3411-12, 3906-07). Dr. Eastwood, an eminent gastroenterologist, testified that Fibre Trim is comparable to other potent fecal bulking fibers, including wheat bran, and is thus an effective laxative (Tr. 3451; RX 179, p. 10).

273. However, even if Dr. Eastwood is correct, Schering did not limit its claims to laxation, but suggested in its advertisements the general importance of fiber, including Fibre Trim, in one's diet, and implied that Fibre Trim would provide the same benefits which the health community discerned in the fiber contained in food. Since Schering stipulated that it would offer no evidence that Fibre Trim had a beneficial effect on cholesterol, coronary heart disease, or diabetes, its health benefit claim was not supported by competent, reliable scientific evidence when it was made.

274. Instead of scientific evidence, Schering relied upon popular press articles praising fiber (Tr. 2232-33, 2425, 2485-86, 2549), and generalized background materials about fiber as support for its health benefits claim (*e.g.*, CX 139 [RX 6]; *see* CX 333, pp. 233-34).

275. Dr. Iezzoni, Schering's Director of Medical Services and the person responsible for the medical review for all package labeling and inserts (Tr. 2402), testified that he did not think it unreasonable to expect that, because Fibre Trim contained fiber, it would provide all of fiber's benefits (Tr. 2549). He sought no further substantiation for Schering's health benefits claim.

276. Dr. Albu believed Schering's health benefits claim to be substantiated because much had been written about the health benefits of fiber, all of which would be applicable to Fibre Trim because "once fiber gets in your body, the body doesn't know

whether it came from broccoli or a tablet, so fiber is fiber in that sense. . . ." (Tr. 2365).

277. Dr. Giaquinto, Schering's chief regulatory executive, and the ultimate person responsible for advertising substantiation review for Schering's Regulatory Department at the time Fibre Trim was first marketed (CX 333, pp. 47, 50-51), could not recall any discussion of support for a claim with regard to Fibre Trim's benefit for any health condition or chronic disease other than weight loss during the review of scientific substantiation for Fibre Trim (CX 333, p. 284). He also testified that in his review of Fibre Trim substantiation, he did not see any scientific support for a claim that Fibre Trim would play a role in reducing the risk for colon cancer (CX 333, p. 261). In fact, Dr. Giaquinto admitted that he never reviewed a number of advertisements that made the health benefits claim (CX 333, pp. 277-79).

#### *H. Substantiation For The High Fiber Claim*

278. Schering's advertising represented that Fibre Trim is a high fiber supplement. The recommended daily dosage (15 tablets) contains about 4.1 grams of fiber (Stipulation of Fact, at paragraph I (F-G)).

279. Schering's recommended dosage of Fibre Trim as a fiber supplement contains less fiber, about 2.5 grams per day (CX 280, CX 357, pp. 2-3; *see* Stipulation of Fact at paragraph I (E)).

280. According to a survey of pharmacists conducted by Schering, 37 percent recommended Fibre Trim to their customers as a fiber supplement (CX 314, p. 2).

281. The FASEB report recommends that the U.S. population increase its fiber intake to 20 to 35 grams per day (CX 90, pp. 1X, 163), and Drs. Story and Anderson testified that this recommendation has been widely accepted and strongly supported by the scientific community (Tr. 491, 3761-62). Most diet recommendations made since the FASEB report have adopted its fiber intake suggestions (Tr. 491).

282. According to Drs. Story and Lanza, Fibre Trim cannot be considered a high fiber supplement since its recommended daily dosage (1.65 to 4.1 grams of fiber) is only 8 to 20 percent of the threshold 20 gram recommendation (Tr. 523, 1360).

283. This argument is based on the presumption that supplements -- of whatever kind -- are taken to satisfy a daily requirement (Tr. 520, 1360), but there is no independent record evidence that persons taking Fibre Trim as a supplement do so in the belief that it will provide the recommended 20 to 30 grams of fiber per day.

284. Fibre Trim's recommended weight loss dosage of 4.1 grams, if equated with a serving of food containing dietary fiber, would qualify as a high fiber source. For example, the FDA has taken the position that products making a fiber claim should meet the following standards: a "source" of fiber should provide at least 2 grams per serving; a "good source" at least 5 grams per serving; and an "excellent source" at least 8 grams per serving (CX 79, p. 1; *see* Tr. 294).

285. Other health organizations in the United States have devised similar classifications for the fiber content of foods. The National Cancer Institute, for example, defines "rich sources" of dietary fiber as those containing four grams or more per serving (CX 156, p. 28; Tr. 1359), and Canadian guidelines state that a "moderate source" of fiber should provide between 2.0 and 4.4 grams of fiber per serving; a "high source" between 4.5 and 6.9 grams per serving; and a "very high" source at least 7.0 grams per serving (Tr. 1271; CX 77, p. 7, CX 78, p. 30).

286. Fibre Trim's weight loss dosage of 4.1 grams of fiber compares favorably, in some cases, with the amount of fiber in a single serving of commonly available foods.

287. Cereals such as All-Bran provide approximately 12 grams of fiber per serving (CX 284, CX 288). According to the Fibre Trim Diet plan, one-half cup of green peas contains 5.0 grams of fiber, one-half cup of spinach contains 5.7 grams, a fresh pear provides 3.7 grams, one-quarter cup of baked beans provides 5.1 grams, one-half cup of kidney beans provides 9.6 grams, and one small ear of corn provides 4.3 grams (Tr. 524-27; CX 284, CX 288, pp. 2-3). A large apple provides approximately 4.2 grams (Tr. 526-27). Breakfast cereals provide roughly four to six grams of fiber per serving (Tr. 2359).

288. The complaint's allegation that Fibre Trim is not a high fiber supplement depends upon the assumption that consumers believe that it provides all of their daily fiber needs -- 20 to 30 grams -- and that the Fibre Trim dosage of 4.1 grams is thus comparatively

low in fiber. This assumption is not supported by reliable record evidence of consumer belief.

289. Complaint counsel make a second assumption: that 5 tablets of Fibre Trim is a "serving" and that its fiber content compares unfavorably with a "serving" of many common foods. This assumption is not unreasonable, but it is equally reasonable to assume that the daily weight loss dosage of Fibre Trim -- 15 tablets -- is a "serving" and that its fiber content compares favorably with that in servings of many foods. I conclude that the full daily dosage of Fibre Trim is equivalent to a serving and that the weight loss dosage is high in fiber. The weight maintenance dosage is, however, not high in fiber.

#### *I. Substantiation For The Fiber Content Claim*

290. In certain advertisements and promotional materials, Schering represented that the recommended dosage of Fibre Trim provides 2.35 grams of dietary fiber per serving, or about seven grams (7.05 grams) per day; however, throughout the time Fibre Trim tablets have been available for purchase in the United States, each Fibre Trim tablet has contained approximately 275 mg. of dietary fiber (Stipulations of Fact at paragraph I (E)). Therefore, a serving of five tablets contains approximately 1.37 grams of dietary fiber, and the daily dosage of fifteen tablets contains approximately 4.1 grams (*id.* at paragraph (D-G)). Thus, Schering overstated its product's fiber content by approximately 71 percent, and had no reasonable basis for its claim that Fibre Trim provides 2.35 grams of fiber per serving, or 7.05 grams per day.

291. In 1986, Schering learned that there had been a misunderstanding with Farma Food regarding the amount of dietary fiber in the Fibre Trim tablet (Tr. 2250, 2363). All Fibre Trim promotional materials were promptly changed to state the correct amount of dietary fiber in each Fibre Trim tablet (Tr. 2250; *see* RX 352).

## III. CONCLUSIONS OF LAW

A. *The Claims Made In Schering's Advertisements*

## 1. Schering's Admissions

Schering admits that its advertisements made the weight loss and weight control or weight maintenance claims (F. 123), the high fiber supplement claim (F. 152) and the fiber content claim (F. 157).

## 2. The Disputed Claims

a. *Introduction*

Schering denies that its advertisements made the appetite suppressant, health benefits and daily requirements claims alleged in the complaint and it argues, with respect to the weight loss claims, that its advertisements inform the consumer that Fibre Trim is only effective if it is used in conjunction with a reduced calorie diet.

If the meaning of an advertisement challenged by the Commission is clear, the Commission and its administrative law judges may, without resort to any evidence other than the language of the advertisement, determine the message which it conveys to reasonable consumers. *Kraft Inc.*, D. 9208 (Jan. 30, 1991), slip op. at 7; *Thompson Medical Co.*, 104 FTC 648, 789 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987); *Cliffdale Associates*, 103 FTC 110, 174, 176 (1984) (Policy Statement on Deceptive Act and Practices ("Deception Statement")).

If the Commission cannot confidently determine its message from the advertisement itself, it will turn to extrinsic evidence, the most convincing of which is direct evidence "of what consumers thought upon reading the advertisement in question." *Thompson Medical*, 104 FTC at 789; *Leonard F. Porter, Inc.*, 88 FTC 546, 626 (1976); *Bristol-Myers Co.*, 102 FTC 21, 319 (1983), *aff'd*, 738 F.2d 554 (2nd Cir. 1984). The extrinsic evidence on which the Commission may rely includes consumer testimony, expert opinion, copy tests of advertisements, or surveys. Deception Statement at 176 n.8.

In this case, the advertisements were directed to upscale females who wanted to lose weight (F. 9-10) and the meaning of the

advertisements should be interpreted from their perspective. *See Bates v. Arizona*, 433 U.S. 350, 383 n.37 (1977).

b. *The Need For Conscious Adherence to a Reduced Calorie Diet*

Many of the Fibre Trim print advertisements do not mention the need to reduce calories (F. 129) and the audio portion of the television advertisements contain no such admonition (F. 127). In fact, several advertisements convey the impression that Fibre Trim itself will help to reduce caloric intake (F. 131) or that there is no need to diet while taking it (F. 126).

Dr. Shimp's expert opinion that the advertisement did not convey to reasonable consumers that conscious adherence to a reduced calorie diet was necessary if Fibre Trim is to be effective (F. 133) is amply supported by the record; indeed, the language of some advertisements is so unequivocal (F. 129) that I conclude with confidence, and without resort to his testimony, that the advertisements contain no such admonition. *See Thompson Medical*, 104 FTC at 789; *Kraft, Inc.*, slip op. at 7, 11.

Other television and print advertisements contain references to diet or reducing plans or sensible eating habits (F. 128, 130, 132, 134, 136-38), but I agree with Dr. Shimp that their language is vague and ambiguous and does not convey the message which Schering claims they do (F. 133-38).

Thus, I agree with Dr. Shimp that despite reference to diet and exercise in some of the Fibre Trim advertisements, the net impression they convey is that adherence to a reduced calorie diet is not essential. Compare *Removatron Int'l Corp.*, 111 FTC 206, 294, *aff'd*, 884 F.2d 1489 (1st Cir. 1989) (despite some admonitory language, the "net impression of these claims is that permanency will be achieved. . . .").

Schering claims that its advertisements did not contain a specific injunction that Fibre Trim should be used in conjunction with a reduced calorie diet because its target audience knew that fact (Schering's Post Trial Brief, p. 20).

It is true that the Fibre Trim advertisements were aimed at upscale women who are presumably more skeptical about advertising promises; however, their desire to lose weight undoubtedly colors their perception of weight loss advertisements and makes them vulnerable to claims about products which promise them an easy road

to success. Schering intended to reach this group of consumers (F. 143). Although the advertisements in *Porter & Dietsch*, 90 FTC 770, 864-65 (1977), *aff'd*, 605 F.2d 294 (2nd Cir. 1979), *cert. denied*, 445 U.S. 950 (1980), were much more positive in their claims about no need for a diet (“No Starvation Dieting. . .”), the Commission’s conclusion in that case is applicable here:

It is obvious that dieting is the conventional method of losing weight. But it is equally obvious that many people who need or want to lose weight regard dieting as bitter medicine. To these corpulent consumers the promises of weight loss without dieting are the Siren's call, and advertising that heralds unrestrained consumption while meeting the inevitable need for temperance, if not abstinence, simply does not pass muster. Where dieting is required, there is simply no substitute for clear and conspicuous disclosure that dieting is required.

Schering’s own research revealed that most of the purchasers of Fibre Trim were looking for a “magic pill” that might obviate the need to diet (F. 143).

I therefore conclude that many Fibre Trim advertisements made no reference to the need to reduce caloric intake and that those which did did not clearly state to reasonable consumers that Fibre Trim would be effective only if it were used in conjunction with a reduced calorie diet. Indeed, some Fibre Trim advertisements conveyed the message that taking Fibre Trim itself would reduce caloric intake.

Schering’s consumer research does not establish that my conclusion is incorrect because it was not designed to determine what messages the specific advertisements at issue conveyed to consumers (F. 139-42). *See Thompson Medical*, 104 FTC at 809 n.34: “In any event, focus groups are not a research tool whose methodology permits use of their results as the basis for drawing generalizable conclusions”; *American Home Products*, 98 FTC 136, 416 (1981), *aff'd*, 695 F.2d 681 (3d Cir. 1982) (open-ended questions do not reveal all claims that may have been perceived in tested advertising).

### c. *The Appetite Suppressant Claim*

Although Schering’s marketing strategy was designed to differentiate it from appetite suppressant drugs, many Fibre Trim advertisements also make the claim that it suppresses appetite (F. 145-50).

Consumer research referenced by Schering which supposedly supports its argument that the advertisements only conveyed to

consumers that Fibre Trim was not a drug like Dexatrim (RPF's 99, 112-13, 122, 132-33, 146, 150) does not do so because it was not designed specifically to determine the messages conveyed to consumers by particular advertisements.

Indeed, the language of the advertisements is so clear -- "takes the edge off hunger"; "helps you control your appetite" (F. 148) -- that one can confidently ignore the testimony of Schering employees and experts who did not perceive an appetite suppressant claim in the advertisements.

*d. The Health Benefits Claim*

References to health in many of the Fibre Trim advertisements were intended to convey the central message that it was different from drug-based diet products (F. 52) (*ITT Continental Baking Co.*, 83 FTC 865, 964-65 (1973); *aff'd*, 532 F.2d 207 (2d Cir. 1976), but other advertisements stressed the health benefits of fiber in addition to its primary use as a weight loss aid (F. 54) and conveyed the message that Fibre Trim provides the health benefits associated with a fiber-rich diet (F. 56).

Whether the health benefits claim was the central or secondary message in Schering's advertisements is irrelevant, for the Commission has held that, if it is deceptive, a secondary claim in an advertisement is illegal even if the primary claim is accurate. *Deception Statement*, 103 FTC at 178 n.21.

The consumer research which Schering points to as establishing that no health benefits claim was made (RPF 85, 100, 110, 126, 144, 153, 158, 163, 174, 177, 190) is not probative on this issue either because it was not designed to and did not elicit responses to particular Fibre Trim advertisements, *see American Home Products*, 98 FTC at 415; *Thompson Medical*, 104 FTC at 794, or because the copy tests tested advertisements which are not alleged to have made the health benefits claim (RPF 105, 110, 153, 158, 163, 190) (F. 75-122).

Although the advertisements do not specify Fibre Trim's health benefits, it is reasonable to infer that consumers will perceive in them benefits which they assume, from other information available to them, that fiber confers (F. 69-74).

*e. The Daily Requirements Claim*

The language cited by complaint counsel in Fibre Trim advertisements and product inserts does not explicitly state that Fibre Trim provides all of a person's daily requirements of fiber (F. 156) and I cannot infer that it makes that claim to reasonable consumers. See *ITT Continental*, 83 FTC at 865, 958-59, where the Commission refused to infer a claim that Wonder Bread supplied all the nutrients in recommended quantities that are essential to healthy growth.

Dr. Levy's opinion that the challenged claim was made is not supported by any specific consumer research and I reject it (F. 156).

*B. Substantiation For Schering's Claims*

1. Introduction

Since consumers would be less likely to rely on product claims if they knew the advertiser did not have a reasonable basis for making them, the Commission requires that advertisers substantiate express and implied claims that make objective assertions about a product. Objective assertions expressly or impliedly represent that the advertiser has a reasonable basis for them. *Thompson Medical*, 104 FTC at 839.

The advertisements in question expressly or impliedly assert that the claims which they make have a scientific basis (F. 158). Compare *Porter & Dietsch*, 90 FTC at 865 ("Laboratory science has perfected. . ."; "clinic tested ingredients. . ."); *Removatron, Int'l*, 111 FTC at 298 ("Clinically tested and endorsed"; "research proves Removatron method destroys hair follicle").

Having made these representations, Schering must establish that it possesses a level of proof which would satisfy the appropriate scientific community that its claims are substantiated. *Removatron Int'l*, 111 FTC at 297; *Thompson Medical*, 104 FTC at 821-22 n.59; *Bristol-Myers Co.*, 102 FTC 21, 321, 331 (1983), *aff'd*, 738 F.2d 554 (2d Cir. 1984), *cert. denied*, 469 U.S. 1189 (1985); *Porter & Dietsch*, 90 FTC at 865.

Schering's advertisements do not expressly or impliedly refer to the substantiation which it possesses; therefore, the adequacy of substantiation for its claims is determined by considering the factors listed in *Pfizer, Inc.*, 81 FTC 23, 64 (1972) and subsequent cases,

e.g., *Thompson Medical*, 104 FTC 839, 840. These factors are: (1) the product involved; (2) the type of claim; (3) the benefits of a truthful claim; (4) the ease of developing substantiation for the claim; (5) the consequences of a false claim; and (6) the amount of substantiation experts in the field would agree is reasonable.

The product. Fibre Trim advertisements assert its efficacy as a weight loss, weight control and appetite suppressant product and make generalized claims about its health benefits. In such a case, the Commission requires a “relatively high level of substantiation, typically scientific tests” *Thompson Medical*, 104 FTC at 822, n.60.

Schering cannot avoid this requirement by claiming that Fibre Trim is a food, not a drug, for it does not have the attributes of a food even though it is derived from natural food sources. See *Nutrilab, Inc. v. Schweiker*, 713 F.2d 335, 338-39 (7th Cir. 1983); *Schering, Inc.*, D. 9232, Order Denying Motion for Partial Summary Decision, May 2, 1990 (ALJ Timony).

The type of claim. Because of the placebo effect, it is difficult for consumers to evaluate Schering’s Fibre Trim claims even if they consume it for an extended period of time (F. 160). Credence claims like these which are “the sort that consumers would not be able to verify easily for themselves” therefore require a high standard of proof such as scientifically adequate clinical trials. *Thompson Medical*, 104 FTC at 822, 823.

The benefit of truthful claims and the ease of substantiation. Considering the cost of conducting two well-controlled clinical trials testing Fibre Trim’s efficacy (F. 159) as compared with the revenues that product has garnered for Schering and the advertising costs it willingly incurred (F. 12), it is not conceivable that requiring Schering to do so would significantly reduce the likelihood that consumers would be denied information about an effective product.

The benefit of truthful claims is obvious, for obesity is a major public health problem (F. 7).

The consequences of a false claim. Since Fibre Trim tablets are expensive (F. 13) and long term use is recommended, the consequences to individual consumers of using an ineffective product for an extended period of time are obvious. The economic harm to consumers, in conjunction with the other factors which the Commission traditionally considers, and which are present in this case, justifies the requirement of substantiation by two well-controlled clinical trials. See *Thompson Medical*, 104 FTC at 824.

Experts in the weight control field testifying in this case confirmed that to establish Fibre Trim's efficacy, at least two well-controlled clinical trials should be conducted (F. 159).

## 2. The Weight Loss, Weight Maintenance And Appetite Suppressant Claims

The three pre-dissemination and four post-dissemination studies on which Schering relies for substantiation of its weight loss and weight maintenance claims did not test the efficacy of Fibre Trim without the simultaneous use of a low calorie diet; in consequence, they do not provide support for the advertised claims -- that Fibre Trim was an effective weight loss and weight maintenance product even if one did not deliberately adhere to a reduced calorie diet.

Since the Fibre Trim studies used subjects who were on diets, the parties' experts, including Dr. Giaquinto of Schering, agreed that they did not establish the truth of the advertised claims (F. 198-99). Therefore, none of the studies substantiate those claims.

Since none of the studies is relevant to any issue in this proceeding, analysis of their scientific validity is unnecessary; however, analysis reveals that the pre-dissemination studies are flawed and do not provide scientific support for Schering's claim, which I reject, that its advertisements told consumers that Fibre Trim was effective only if used in conjunction with a reduced calorie diet.

Hessel was not placebo controlled or blinded, and it can be dismissed from consideration (F. 208). The treatment in Rytzig of withdrawals (F. 212-13) gives me pause with respect to its soundness. The most significant defect in this study is, however, its use of almost twice as much Fibre Trim as the recommended dosage. Since its results -- however valid -- cannot support the claim made for the recommended dosage (F. 210), it provides no support for the advertised weight loss claims.

The description of Solum I's protocol was so scanty that Schering's acceptance of its results was not prudent (F. 214-17).

The three studies relied on by Schering are fundamentally flawed and do not meet the standards for a well-controlled clinical test. *See Thompson Medical*, 104 FTC at 828.

At the time of dissemination of the challenged advertisements, Schering personnel who were responsible for analyzing the data supporting its claims were aware of, or should have been aware of,

other evidence, beside the Hessel, Solum I and Rytting studies, which cast doubt on the efficacy of weight loss aids, including Fibre Trim.

In August 1984, Schering knew that there was an additional Fibre Trim study which did not show a significant difference between fiber tablets and placebo (F. 186). Schering never asked Farma Food for this study (F. 187) or other studies which cast doubt on the efficacy of Fibre Trim as an appetite suppressant or aid to weight loss (F. 188-90).

Furthermore, reputable scientific bodies, both before and after dissemination of the advertisements, were skeptical about the efficacy of fiber as a weight loss aid. The FDA's 1982 proposal to establish a weight loss monograph stated that the value of bulk producers like Fibre Trim had not been established (F. 196).

Although the Ehmann & Ressin, Solum II, Rossner and Birketvedt studies were obtained by Schering after dissemination of the challenged advertisements, they are put forward as providing independent scientific support for its claims as well as confirmatory support for the conclusions of the pre-dissemination studies. I reject Schering's argument for two reasons.

First, the studies provide only shaky support for Schering's claims: Dr. Feinstein testified that Ehmann & Ressin is not an acceptable study because it was not randomized or blinded (F. 219); Solum II used 20 Fibre Trim tablets rather than 15, the recommended dosage (F. 221); Dr. Levitsky's reanalysis of Rossner excluding dropouts reveals that placebo subjects actually lost more weight than the fiber subjects and the initial analysis of this study showed no statistically significant difference between placebo and Fibre Trim groups (F. 191, 225, 228); and the Birketvedt study did not show a statistically significantly weight loss at its conclusion (F. 231).

The second reason for dismissing these studies is that they cannot, as a matter of law, be considered as substantiation for the claims because they were conducted after the claims were made. *Removatron Int'l*, 111 FTC at 303, 305. The only limitation to this doctrine is discretionary: the Commission may consider them if they "shed light on pre-claim substantiation." *Id.* at 841. These studies do not do so for they are so flawed what they do not provide support, in and of themselves, for the weight loss claim. Nor do they or the pre-dissemination studies provide support for the weight maintenance and appetite suppressant claims (F. 200-01). In conclusion, I agree with Drs. Levitsky and Levine that the pre- and post-dissemination studies

do not support the claims that Fibre Trim is an effective weight loss or weight control product (F. 233).

### 3. The Health Benefits Claim

While the health benefits statements in Schering's advertisements did not detail the problems on which Fibre Trim might have some beneficial or preventative effect, it is not unreasonable to infer that consumers would associate them with heart disease, colon cancer and digestive ailments (F. 69, 71, 73, 74). The claims were, therefore, objective and Schering should have possessed and relied upon a reasonable basis for them.

Although there is scientific consensus that fiber does provide some health benefits (F. 252-53), Schering's assumption that the fiber in Fibre Trim and the fiber in foods provide the same benefits is not supported by present scientific opinion and Schering, therefore, had no scientific substantiation for a generalized health benefits claim (F. 254-57).

The laxation studies are not without faults, but they appear to show that Fibre Trim may have some laxative effect (F. 268-72); however, these studies were limited to one health problem and provide no substantiation for the other health benefits claims involving cholesterol, coronary heart disease and cancer (F. 273, 277). Schering's reliance on press articles praising fiber (F. 274) does not satisfy the standards established by the Commission for proof of efficacy.

### 4. High Fiber and Fiber Content Claims

The daily Fibre Trim dosage for weight loss (15 tablets) provides 4.1 grams of fiber. This is a high amount of fiber (F. 278-89). Schering's claim with respect to the fiber content of the weight loss dosage is, therefore, not false or unsubstantiated. The daily weight maintenance dosage of Fibre Trim does not provide a high amount of fiber (F. 289) and representations to that effect were untrue and unsubstantiated, as were representations as to the amount of fiber in a Fibre Trim tablet.

### *C. Materiality Of The Claims*

The lack of substantiation for Schering's health benefits, weight loss and weight maintenance claims was material, for they involved "health, safety, or other areas with which the reasonable consumer would be concerned." *Cliffdale Associates*, 103 FTC at 182. The high fiber and fiber content claims were express; therefore, they are presumptively material. *Ibid.* Schering has offered no convincing evidence rebutting this presumption.

### IV. SUMMARY

1. Schering has advertised, offered for sale, sold, and distributed Fibre Trim to the public as a high fiber supplement, and as a weight loss and weight maintenance product.

2. For the purposes of Section 12 of the FTC Act, 15 U.S.C. 52, Fibre Trim is a drug or food as defined in Section 15 of the Act, 15 U.S.C. 55.

3. The acts and practices of Schering challenged in the complaint have been in, or affect, commerce.

4. The Commission has jurisdiction over respondent Schering, and the acts and practices challenged in the complaint.

5. Through statements in advertisements and promotional materials, Schering represented, directly or by implication, that Fibre Trim is an effective appetite suppressant, weight loss, weight control or weight maintenance product, and that Fibre Trim provides the health benefits associated with a fiber-rich diet or a high intake of dietary fiber from food.

6. Schering represented, directly or by implication, that at the time it made the representations in paragraph five, it possessed and relied upon a reasonable basis for such representations.

7. At the time Schering made the representations in paragraph five, it did not possess and rely upon a reasonable basis for them.

8. Schering further represented in advertisements or promotional material that Fibre Trim is a high fiber supplement and that the recommended dosage of Fibre Trim provides about 2.35 grams of dietary fiber per serving.

9. In fact, the Fibre Trim weight maintenance dosage is not high in fiber and the recommended dosage of Fibre Trim does not provide

almost 2.35 grams of dietary fiber per serving, and Schering's representations to the contrary were false and misleading.

10. The above acts and practices of Schering, which induced consumers to purchase substantial quantities of Fibre Trim, constitute unfair or deceptive acts or practices in violation of Sections 5(a) and 12 of the FTC Act.

#### V. THE ORDER

Over an extended period of time, and in the face of "murky" clinicals (F. 195), and contrary scientific evidence, Schering knowingly advertised and promoted Fibre Trim as an effective weight loss, weight control or weight maintenance product, and consumers were not adequately informed that Fibre Trim might be effective only if taken as part of a reduced calorie diet.

The sales of Fibre Trim have been substantial, indicating extensive consumer reliance on Schering's misrepresentations about its weight loss, weight control and health benefits attributes.

Under these circumstances, complaint counsel's proposed extension of the order beyond that which accompanied the complaint is warranted.

Specifically, Part I of the order would prohibit future misrepresentations (a) about the quantitative or qualitative fiber content or other nutrient or dietary component content of Fibre Trim or any other food, food supplement or drug, or (b) that the product is a high source of fiber, or any other nutrient or dietary constituent. This broadening of the notice order is appropriate in this case. *See Kraft, Inc.*, slip op. at 1, 29-30.

Part II(b) of the order modifies the notice order by stating that, for purposes of any representation that a fiber supplement or other food supplement or drug is an effective appetite suppressant or effectuates weight loss, weight maintenance, or weight control through appetite reduction or any other physiological mechanism, "competent and reliable scientific evidence" shall mean at least two independent, adequate and well-controlled double-blind clinical studies demonstrating the efficacy of the product. This definition is based upon the standard required in the Commission's order in *Thompson Medical*, 104 FTC at 844.

Even if, as Schering argues, Fibre Trim is a food and not a drug, the substantiation standard established in *Thompson Medical* is

appropriate. *See Removatron*, 111 FTC at 310 where the Commission required clinical testing for hair removal products which respondent claimed were cosmetic devices which did not affect public health or safety; *see also North American Phillips Corp.*, 101 FTC 359, 364 (1983) (two clinicals required for claims that electric razors alleviated "razor bumps").

The two trial requirement is consistent with the FDA's Advance Notice of Proposed Rulemaking which includes a proposed protocol for evaluation of weight control products requiring that their efficacy be established by two independent studies (CX 81, pp. 16-19).

The order does not require a specific clinical testing requirement for purposes of the remaining representations covered by Part II. These claims must be substantiated by competent and reliable scientific evidence, defined as "tests, analyses, research, studies, or other evidence conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted by others in the profession or science to yield accurate and reliable results." This definition is consistent with the Commission's recent order in *Kraft, Inc.*, slip op. at 2.

The disclosure requirement of Part III of the order tracks the similar disclosure requirement in *Campbell Soup Co.*, D. 9223 (consent agreement, April 8, 1990).

The multi-product provision of the order is amply justified by Schering's health-related misrepresentations about Fibre Trim, for they were serious, were made repeatedly in an extensive six-year promotional campaign, and are readily transferable to the advertising of other Schering products. *See Kraft, Inc.*, slip op. at 30; *American Home Prods.*, 695 F.2d 681, 707 (3d Cir. 1982); *Litton Industries*, 676 F.2d 364, 372 (9th Cir. 1981); *Thompson Medical*, 104 FTC at 833.

The violations were serious because the weight loss and weight control claims were consciously made despite flaws in the studies relied upon by Schering, and because consumers who were not able to assess the validity of those claims relied on the misrepresentation that Fibre Trim had been proven to be effective. *See Thompson Medical*, 104 FTC at 834. Therefore, the following order is appropriate.

## I.

*It is ordered,* That respondent Schering Corporation, a corporation, its successors and assigns, and its officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, labeling, packaging, offering for sale, sale or distribution of Fibre Trim or any other food, food supplement or drug in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from misrepresenting, directly or by implication:

- a. The amount of fiber or any other nutrient or dietary constituent contained in the product, whether described in quantitative or qualitative terms; and
- b. That the product is a high, rich, excellent or superior source of fiber or any other nutrient or dietary constituent using those words or words of similar meaning.

## II.

*It is further ordered,* That respondent, its successors and assigns, and its officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, labeling, packaging, offering for sale, sale or distribution of any food, food supplement or drug in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, directly or by implication:

- a. Regarding the actual or comparative amount of fiber or the type(s) of fiber, or the actual or comparative amount of any other nutrient or dietary component in the product;
- b. That the product provides any appetite suppressant, weight loss, weight control, or weight maintenance benefit; or
- c. That the product provides any health benefit associated with the intake of fiber, or any other nutrient or dietary component;

unless, at the time that it makes such representation, respondent possesses and relies upon competent and reliable scientific evidence

that substantiates the representation. For purposes of this order, "competent and reliable scientific evidence" shall mean those tests, analyses, research, studies, or other evidence conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted by others in the profession or science to yield accurate and reliable results.

Provided that, for purposes of any representation covered by subpart (b) of this part that a fiber supplement or any other food supplement or drug is an effective appetite suppressant or that it effectuates weight loss, weight control, or weight maintenance through reduction in appetite or any other physiological mechanism, "competent and reliable scientific evidence" shall mean at least two adequate and well-controlled, double-blinded clinical studies that conform to acceptable designs and protocols and are conducted by different persons, independently of each other. Such persons shall be qualified by training and experience to conduct such studies.

Provided further, with respect to any representation covered by the first proviso of this part, if the Food and Drug Administration promulgates any final standard that establishes conditions under which such product is safe and effective under the Food, Drug and Cosmetic Act, then in lieu of the above, respondent may rely upon scientific evidence that fully conforms to such final standard as a reasonable basis for said representation.

### III.

*It is further ordered,* That respondent, its successors and assigns, and its officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, labeling, packaging, offering for sale, sale or distribution of any food, food supplement or drug in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, shall, whenever a product's fiber content is described in advertising or labeling, directly or by implication, in quantitative or qualitative terms, disclose clearly and prominently in immediate proximity to such description the number of grams of dietary fiber contained per serving of the product, unless such fiber content descriptor is a term defined by the Food and Drug Administration in labeling regulations under the Food, Drug and

Cosmetic Act, in which case compliance with said regulations will be deemed compliance with Part III of this order.

IV.

*It is further ordered*, That, for three (3) years from the date that the representation is last disseminated, respondent shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

1. All materials that were relied upon to substantiate any representation covered by this order; and
2. All test reports, studies, surveys, demonstrations or other evidence in respondent's possession or control, or of which it has knowledge, that contradict, qualify, or call into question such representation or the basis upon which respondent relied for such representation.

V.

*It is further ordered*, That respondent shall notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporation which may affect compliance obligations arising out of the order.

VI.

*It is further ordered*, That respondent shall forthwith distribute a copy of this order to each of its current operating divisions and to all distributors of products covered by this order.

VII.

*It is further ordered*, That respondent shall, within sixty (60) days after service of this order upon it and at such other times as the Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied or intends to comply with this order.

## DECISION AND ORDER

The Commission having heretofore issued its complaint charging the respondent named in the caption hereof with violation of Sections 5 and 12 of the Federal Trade Commission Act, as amended, and the respondent having been served with a copy of that complaint together with a notice of contemplated relief; and

The respondent, its attorney, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true and waivers and other provisions as required by the Commission's Rules; and

The Secretary of the Commission having thereafter withdrawn this matter from adjudication in accordance with Section 3.25(b) of its Rules; and

The Commission having considered the matter and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, now in further conformity with the procedure prescribed in Section 3.25(f) of its Rules, the Commission hereby makes the following jurisdictional findings and enters the following order:

1. Respondent Schering Corporation is a corporation organized, existing and doing business under and by virtue of the laws of the State of New Jersey, with its office and principal place of business located at 2000 Galloping Hill Road, in the City of Kenilworth, State of New Jersey.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

## ORDER

## I.

*It is ordered,* That respondent Schering Corporation, a corporation, its successors and assigns, and its officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, labeling, packaging, offering for sale, sale or distribution of Fibre Trim or any other food, food supplement or drug in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any misrepresentation, directly or by implication:

- a. About the amount of fiber or any other nutrient or dietary constituent contained in the product, whether described in quantitative or qualitative terms; or
- b. That the product is a high, rich, excellent or superior source of fiber or any other nutrient or dietary constituent using those words or words of similar meaning.

Provided that nothing in this Part shall prohibit any representation as to the amount of fiber or any other nutrient or dietary constituent in any product if such representation is specifically permitted in labeling, for the serving size advertised or promoted for such product, by regulations promulgated by the United States Food and Drug Administration (FDA) pursuant to the Nutrition Labeling and Education Act of 1990.

## II.

*It is further ordered,* That respondent, its successors and assigns, and its officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, labeling, packaging, offering for sale, sale or distribution of any food, food supplement or drug in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, directly or by implication:

- a. Regarding the actual or comparative amount of fiber or the type(s) of fiber, or the actual or comparative amount of any other nutrient or dietary constituent in the product;
- b. That the product provides any appetite suppressant, weight loss, weight control, or weight maintenance benefit; or
- c. That the product provides any health benefit associated with the intake of fiber, or any other nutrient or dietary constituent;

unless, at the time that it makes such representation, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation. For purposes of this order, "competent and reliable scientific evidence" shall mean those tests, analyses, research, studies, or other evidence conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted by others in the profession or science to yield accurate and reliable results.

Provided that, for purposes of any representation covered by subpart (b) of this Part that a fiber supplement or any other food supplement or drug is an effective appetite suppressant or that it effectuates weight loss, weight control, or weight maintenance through reduction in appetite or any other physiological mechanism, "competent and reliable scientific evidence" shall mean at least two adequate and well-controlled, double-blinded clinical studies that conform to acceptable designs and protocols and are conducted by different persons, independently of each other. Such persons shall be qualified by training and experience to conduct such studies.

Provided further, that nothing in this order shall prohibit respondent from making any representation for any drug that is permitted in labeling for any such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

Provided further, that nothing in subparts (a) or (c) of this Part shall prohibit respondent from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the FDA pursuant to the Nutrition Labeling and Education Act of 1990.

## III.

*It is further ordered,* That respondent, its successors and assigns, and its officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, labeling, packaging, offering for sale, sale or distribution of any food, food supplement or drug in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, shall, whenever a product's fiber content is described in advertising or labeling, directly or by implication, in quantitative or qualitative terms, disclose clearly and prominently in immediate proximity to such description the number of grams of dietary fiber contained per serving of the product.

Provided that if such fiber content descriptor is a term defined by regulations promulgated by the FDA pursuant to the Nutrition Labeling and Education Act of 1990, compliance with said regulations will be deemed compliance with Part III of this order.

## IV.

*It is further ordered,* That, for three (3) years from the date that the representation is last disseminated, respondent shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

1. All materials that were relied upon to substantiate any representation covered by this order; and
2. All test reports, studies, surveys, demonstrations or other evidence in respondent's possession or control, or of which it has knowledge, that contradict, qualify, or call into question such representation or the basis upon which respondent relied for such representation.

## V.

*It is further ordered,* That respondent shall notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporation which may affect compliance obligations arising out of this order.

## VI.

*It is further ordered,* That respondent shall, within thirty (30) days after service of this order, distribute a copy of this order to each of its operating divisions responsible for the preparation or placement of advertisements, promotional materials, product labels, or other such sales materials covered by this order.

## VII.

*It is further ordered,* That respondent shall, within sixty (60) days after service of this order and at such other times as the Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied or intends to comply with this order.

Commissioner Varney not participating.